APPENDIX

In the Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-605

UNITED STATES OF AMERICA, ET AL.,
Petitioners

—*v.*—

GLEN L. RUTHERFORD, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES
COURT OF APPEALS FOR THE TENTH CIRCUIT

PETITION FOR WRIT OF CERTIORARI FILED OCTOBER 10, 1978
CERTIORARI GRANTED JANUARY 22, 1979

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ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

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Closed Dec. 5, 1977

RUTHERFORD, GLEN L., PLF INTERVENOR

and

STOWE, JIMMIE, and SCHNEIDER, GENE, individually and on behalf of a class composed of cancer victims and their spouses, who are responsible for the costs of treatment, ORIGINAL PLAINTIFFS

WARD, IRENE, INTV. 1-8-76

v.

UNITED STATES OF AMERICA and WEINBERGER, CASPER, Secretary of Health, Education and Welfare, DEFENDANTS

DATE	INTERVENERS
1-26-76	Ruth O. Aldrich
4-23-76	LaVerne Martin
4-23-76	Helen W. Wallace
4-23-76	Hazel Ward Ahrens
5-24-76	Charles Eugtne Gassaway
6-3-76	Barbara C. Hopping
6-10-76	David M. Davis
6-23-76	Tom Covington
11-26-75	Ernest Ray
6-24-76	Donna Vivian Auer
7-9-76	Phillip C. Ferguson
7-9-76	Myrtle M. McCluskey
7-9-76	Helen Hook
7-15-76	Edna May Ingram
8-4-76	Juanita Loftiss
8-4-76	Mary Ferris
8-12-76	Helen B. Wilson
9-22-76	Muriel R. McWilliams
9-22-76	Orian T. Carroll
10-6-76	Sidney Elmer White
10-6-76	Corie Lynn Mudd

DATE	INTERVENERS
10-26-76	Eric Weber
10-29-76	Karl S. L. Leimer
11-8-76	Kyle Don Nelson
11-11-76	Evelyn Marie Rowland
11-15-76	Elbert T. Howell
12-6-76	Mildred E. Hutchins
12-6-76	Dana Ackerman
12-6-76	Anna Mae Lemke
12-7-76	Lee A. Mackey
12-15-76	Dave Kerr
12-16-76	Leo Hodges
12-16-76	Beatrice Meo
12-17-76	Jamie Holzen
12-17-76	Helen A. Nay
12-22-76	Charlene Kratzer
1-4-77	Margarite E. Perrigue
1-6-77	Ruby Jones Wren
1-11-77	Mrs. G. E. (Irma) Evans
1-17-77	Margaret Emde
2-4-77	Teddie M. Baird
2-7-77	Harry O'Keefe
2-7-77	Robert E. Taylor
2-15-77	Ilona Laszlo
2-15-77	James M. Scarborough
12-23-76	Evone Hollie
12-27-76	Mary Alice Sibel
12-30-77	Luella Kamphaus
1-18-77	Mabel Kays
1-18-77	Eleanor Elizabeth Timmons
1-20-77	Leo Elizabeth Boren
2-17-77	Robert Vernon McGuire
2-23-77	V. Kay Christopher
2-28-77	Juanita Wickham
3-8-77	Robert Perry Moss
3-28-77	Belle Gilliam
3-25-77	Lester Trilla
4-7-77	Bernadette Ortell
4-11-77	Frances Maureen Deal
4-12-77	Joy Marie Chastain
4-19-77	Billie Ann Jenkins

DATE	PROCEEDINGS
3-12-75	Filed Complaint
3-12-75	Filed prae for & issued summons
3-14-75	Ent hrg on plf's appl for a prel. inj.: (Daugherty) ve (appl for prel. inj. cont'd at (req. of plf; to be reset at
6-30-75	Filed plfs' Appl for Lv to File Amended Complaint ws
6-30-75	Ent Order granting plfs' appl for lv to file amended compl; dfts directed to ans or plead w/in 60 days (Daugherty) ve ws
6-30-75	Filed plfs' Amended Complaint, adding plfs (see caption)—ns shown
7-3-75	Filed plfs' Glen Rutherford, Gene W. Schneider & Phyllis S. Schneider Appl for Temporary Order—ws
7-11-75	Ent Hrg on Temp Rest'g Order; statements made; pltf presents appl w/test of witnesses & reses; plf's exhibits 1-8 admitted; plf to file brief 7-15-75; case set for hrg 7-18-75, 9:30 a.m. (Bohanon) sjb
8-14-75	Filed Findings of Fact & Conclusions of Law (Bohanon)
8-29-75	Filed dfgts' Mtn to Dsms—ws (Memo in Supt attached)
9-4-75	Filed Order Denying dfts' 2nd Mtn to Dsms filed 8-29-75 (Bohanon) ws, sjb
10-3-75	Filed dfts' Mtn for Stay & Brief in Supt Thereof—ws
10-6-75	Filed Order that dft's Mtn to Stay Ct's Order of 8-14-75 is denied (Bohanon) ws, sjb
10-8-75	Filed dft's Notice of Appeal from Order entered Aug 14, 1975 (record due in CCofA 11-17-75)
10-10-75	Filed Order On Style of Case setting forth new style of case (copies

DATE	PROCEEDINGS

11-24-76 Filed copy of CCofA's Opinion

1-24-76 Filed cert copy of CCofA's Mandate (judg affirmed insofar & only insofar as it grt the prel inj which we hold can cont in effect purs to 5 USC § 705; the cause is remanded to the USDC for thw [sic] WD of Ok for further proceedings consistent w/the views expressed in the opinion of this ct) (Holloway, McWilliams & Doyle) (CCA #75-1725) ws

12-30-76 Ent pretrial hearing—Statements made; pt stricken; case to be remanded to FDA for hrg. Ct to prepare order; dft to furnish ct & plfs information on file with FDA in 60 days (Bohanon) sjb

1-4-77 Filed Memorandum Opinion & Order THAT dft FDA is enjoined & restrained fr preventing plfs' importation or interstate transp. of Laetrile for purposes of their own consumption under the terms of the F & D Act, incld'g ¶ 505(a) of the Act, 21 USC ¶ 355(a); that on remand an administ. record shall be developed w/i 120 dys herefrom & a copy shall be filed w/Clk of Ct & plfs w/i 30 days thereafter

3-18-77 Ent Hrg on plf appl. to clarify class (Evid. Hrg): statement made; plfs rests; dft presents obj. w/list of witness; parties rest; argmts hrg; plf to submit proposed order as to class; plf to file reply brief in 10 days; case to be set for further argument. (Bohanon) sjb

4-8-77 Filed Memo Opinion (Bohanon) ws

4-8-77 Filed *AND ENTERED* Order And Decree—THAT plf class is certified as encompassing all "terminally ill cancer patients"; the phrase "terminally ill cancer patient refers to anyone who, in aff form as hereafter described is declared by a practicing physician (M.D.) to be terminally ill; such aff to incl things as more fully set out; that dfts, et al, are enj'd from impeding or preventing the importation & interstate transportation of laetrile by any members of the plf class or their duly designated agents; that such laetrile can be imported & utilized

DATE	PROCEEDINGS

solely for the pers use & benefit of the plf class members; Clk to send, by reg mail, a cert copy hereof to ea dept administrator referred to herein (Bohannon) (COB #119) (Clerk) (Copies to parties—sjb)

5-9-77 Ent Hrg on Plf's Mtn for Contempt; stmts made; dft's Exh #1 adm; case passed to 5-10-77, 10am (Bohanon) sjb

5-10-77 Ent Hrg on clarification of Aff; stmts made; parties stip, ct files order (Bohanon) sjb

5-10-77 Filed Order on Aff & Ext; that the attchd aff will suffice & be sufficient for any cancer patient to have, receive & transport laetrile for his or her own use under the class action prev certified by the Ct on 4-8-77; the quantity of laetrile so had, received & transported shall be a 6 mo's supply not to exceed 750 tabs at 500 mlg per tab & 1500 cc's of injectable liquid; that the plf's mtn for contempt citation is moot; directed that the FDA disseminate a copy hereof & the attchd aff for the benefit of all concerned; that the req of the FDA for a 90 day ext to file it's adm record & report is grtd (Bohanon) ws

6-23-77 Filed Order that Dr. Mario A. Soto & Dr. Raul Morales Aceves are auth'd to execute affs as defined in the ct's order of 5-10-77, & that such affs will qualify the class member named in the aff to import & transport laetrile interstate under the terms & conditions of this ct's order of 5-10-77; that the FDA disseminate a copy hereof in the same manner & for the same purposes that the ct's order of 5-10-77 was disseminated (Bohanon) ws

7-12-77 Filed Order Allowing Certain Mexican Doctors to Execute Affs Indentifying Plf Class Members—that Dr. Ernesto Contreras & Dr. Abel Mallado Prince are author'd to execute affs as defined in the ct's order of 5-10-77, & that such affs will qualify the class member named in the aff to import & transport laetrile interstate under the terms & conditions of the ct's 5-10-77, order; that the

DATE	PROCEEDINGS

FDA disseminate a copy of this order in the same manner & for the same purposes that the ct's order of 5-10-77, was disseminated; that dfts are granted 10 days w/in which to file any formal objs to this order; The Ct will hrg evid & oral arguments upon dft's req (Bohanon) w/s-sjb

8-4-77 Filed FDA's Administrative Record -ws consisting of 523 exhs, over 5000 pages

8-19-77 Filed Aff of Gerald M. Rachanow

8-31-77 Filed Supplemental Stip Order (Bohanon) (copies mailed-mc)

10-4-77 Filed Order—It is Stip between the plf & dft, U.S. Customs Service, that the 30 day grace period granted in parag 1 of the Supplemental Stip order filed 8-31-77 is extended to & including the 31st day of October, 1977. This extension is based upon representations that it has been impossible to obtain a customs bond even though diligent effors have been made. See Aff of J. Franklin Salaman & letter of Ferd L Hershfield attached hereto as Exh A & B (Bohanon) (copies mailed & delivered-ih)

11-11-77 Filed Order—It is agreed by & between plf & dft, U.S. Customs Service, that the provisions of the Ct orders of 8-22-77 & 8-31-77 as they pertain to Customs' bonding requirements are hereby con't in effect until such time as the U.S. Dist Ct for the WD of Okla. rules upon the administrative record complied by the Federal Food & Drug Administration & heretofore submitted to the Ct for judicial review (Bohanon) (copies mailed/delivered-wwm)

11-28-77 Filed Plf's Mtn for Preliminary Injunction -w/s

12-5-77 Filed Ct's Opinion (Bohanon) ns

12-12-77 Filed Notice of Appeal of dfts from final jdgmt entered Dec 5, 1977 (record due in CCofA 1-23-78)

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

CIV—75-0218-D

[Filed March 12, 1975]

JUANITA IRENE STOWE and
JIMMIE STOWE, Husband and Wife, PLAINTIFFS

vs.

UNITED STATES OF AMERICA and CASPER WEINBERGER,
Secretary of Health, Education and Welfare, DEFENDANTS

COMPLAINT

For cause of action against the Defendants, Plaintiffs respectfully show to the Court:

I.

PARTIES AND JURISDICTION: The parties to this action and the facts which establish jurisdiction of this Court are:

1. *Plaintiffs*: Juanita Irene Stowe and Jimmie Stowe, husband and wife, are residents of Oklahoma.

2. *Defendants*: The United States of America (hereafter "USA"); and Casper Weinberger, Secretary of Health, Education and Welfare of the United States of America, (hereafter "SECRETARY"). Defendant, SECSETARY, supervises the United States Food and Drug Administration (hereafter "FDA").

3. The Plaintiffs are seeking relief under the Fifth and Fourteenth Amendments to the Constitution of the United States, under the Federal Food, Drug and Cosmetic Act, 21 USC 1/392, and the Administrative Procedure Act, 5 USC 701, Sec. 2. By reason of the actions of the SECRETARY as hereafter set forth, the rights of Plaintiffs, under the Constitution of the United States and under the above statutes have been violated, to the

extent that Plaintiffs are entitled to judicial relief in this cause; and this Honorable Court has jurisdiction over the parties to and subject matter of this action.

II.

RELATIONSHIP OF PARTIES: By reason of action heretofore taken by the SECRETARY under and pursuant to 21 USC 355, a vitamin substance (B-17, also identified as Laetrile and Amygdalin) has been considered by the SECRETARY as a "new drug" within the definition of 21 USC 321(p); and the SECRETARY has, by a series of proceedings known to the SECRETARY, but unknown to Plaintiffs issued orders and regulations which preclude the dispensing of the said vitamin substance to persons suffering from cancer, upon the stated ground that the efficacy of the substance had not adequately been proven as a cancer remedy, and its use as a segment of anti-cancer therapy could have the result of precluding persons suffering from cancer from receiving other treatments recognized by the medical profession, and the use of other drugs approved by the SECRETARY.

III.

CAUSE OF ACTION: Plaintiffs state that the Plaintiff, JUANITA IRENE STOWE, is suffering from cancer of the brain and lung; and is presently confined to Deaconess Hospital in Oklahoma City, Oklahoma, where she and the Plaintiff, JIMMIE STOWE, are incurring extensive financial obligations for her treatment with no hope of ultimate relief. Plaintiffs state that, because of the order and regulation of the SECRETARY, the Plaintiff, JUANITA IRENE STOWE, is unable to have nurses and doctors affiliated with the hospital administer to her B-17/Laetrile, which she has in her possession, and elects to use for the purpose of creating within her body a metabolic enzymatic reaction that would expose the cancer infested trophoblast cells to the destructive force of her body's white blood cells, thus permitting natural reactions of her body to control the out-of-phase reactions of the cancerous trophoblast cells in Plaintiff's body.

Plaintiffs state that the "liberty" protected by the Due Process Clause of the Fifth and Fourteenth Amendments to the Constitution of the USA would preclude the USA, acting by and through the SECRETARY, from invading the vital right of Plaintiff, JUANITA IRENE STOWE, to assert a freedom of choice in requesting the administration of an injection into her body of B-17/Laetrile for the purpose of accelerating her natural metabolic reactions, so long as such election of remedy on her part is taken with full knowledge of all scientific analyses presented by the SECRETARY, through the FDA. Plaintiffs further state that there has been no FDA analysis of B-17/Laetrile that would indicate lethal or even adverse effects upon the human body; but Plaintiff is denied her Constitutional right and liberty to obtain such treatment, solely by an FDA report that B-17/Laetrile had not yet been adequately proven as an effective anti-cancer therapy. With this information fully known to Plaintiffs, they would have a constitutional freedom of choice to request the administration of B-17/Laetrile; and an Order of this Honorable Court is sought to prevent the Defendant, SECRETARY, through the HEW and FDA, from precluding and restricting Plaintiff's liberty in a knowing freedom of choice to obtain Vitamin B-17/Laetrile treatment as above set forth. Plaintiffs state that the action of the SECRETARY, in arbitrarily and capriciously, through HEW and FDA, precluding and restricting Plaintiffs' liberty of a knowing freedom of choice to obtain Vitamin B-17/Laetrile treatment as set forth above are a violation of Plaintiffs' constitutional rights; and such action of the SECRETARY, in the arbitrary and capricious exercise of administrative judgment, to deny dying people a freedom of choice to obtain B-17/Laetrile treatments, when a pregnant [sic] has been recognized as having a freedom of choice to demand an abortion is a denial of Plaintiffs' constitutional rights including equal protection of the law, as well as denial of similar constitutional rights of other citizens of the USA.

IV.

REQUESTED RELIEF: Plaintiffs state, that, by reason of the actions of the SECRETARY, as above set forth, and deprivation of Plaintiffs constitutional rights, Plaintiffs have no adequate remedy at law and are entitled to equitable relief as follows:

1. Judgment herein ordering and directing the SECRETARY to cease and desist from enforcement of order of FDA precluding the administration of Vitamin B-17/ Laetrile to patients suffering from cancer.

2. In addition, and as ancillary relief, Plaintiffs are entitled to declaratory judgment under and pursuant to 28 USC 2201, as an enlargement upon the Plaintiffs' remedy against the SECRETARY, upon the ground of existence of an actual controversy within the jurisdiction of this Court, not involving Federal taxes; and Plaintiffs are entitled to a declaration and adjudication that the action of the SECRETARY in denying to Plaintiffs the right to have injections and dosages of Vitamin B-17/ Laetrile is an unconstitutional denial and invasion of Plaintiffs' rights and liberties, under the Constitution of the USA.

3. Plaintiff, JUANITA IRENE STOWE, is now in a very critical condition, facing imminent death; and in order to assert her Constitutional rights to take advantage of the therapy to which she is entitled as an American Citizen, respectfully requests an early hearing for a temporary order to permit administration to her of B-17/Laetrile, both interveneously and orally until this cause can be tried on its merits.

WHEREFORE, Plaintiffs pray judgment herein against the USA and the SECRETARY, as follows:

1. Judgment herein ordering and directing the SECRETARY to cease and desist from enforcement of order of FDA precluding the administration of Vitamin B-17/ Laetrile to patients suffering from cancer.

2. In addition, and, as ancillary relief, Plaintiffs are entitled to declaratory judgment under and pursuant to 28 USC 220k, as an enlargement upon the Plaintiffs'

remedy against the SECRETARY, upon the ground of existence of an actual controversy within the jurisdiction of this Court, not involving Federal taxes; and Plaintiffs are entitled to a declaration and adjudition that the action of the SECRETARY in denying to Plaintiffs the right to have injections and dosages of Vitamin B-17/ Laetrile is an unconstitutional denial and invasion of Plaintiffs' rights and liberties, under the Constitution of the USA.

3. That the Court fix an early date for a hearing of Plaintiffs' Application for temporary relief; and that Defendants be ordered to show cause why a temporary order should not be entered authorizing and directing the administration of B-17/Laetrile to Plaintiff, JUANITA IRENE STOWE, pending further order of the Court in this cause.

4. That Plaintiffs have such further judgment and relief, as may appear just and proper.

/s/ Clyde J. Watts
CLYDE J. WATTS
Attorney for Plaintiffs

OF COUNSEL:

WATTS, LOONEY, NICHOLS,
JOHNSON & HAYES
219 Couch Drive
Oklahoma City, Oklahoma 73102
(405) 235-7641

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

No. CIV—75-0218-D

[Filed June 30, 1975]

JIMMIE STOWE, Surviving husband of JUANITA STOWE, Deceased; GLEN L. RUTHERFORD; and GENE W. SCHNEIDER and PHYLLIS S. SCHNEIDER, husband and wife, individually and on behalf of a class composed of cancer victims and their spouses, who are responsible for the costs of treatment, PLAINTIFFS

vs.

UNITED STATES OF AMERICA and CASPER WEINBERGER, Secretary of Health, Education and Welfare, DEFENDANTS

AMENDED COMPLAINT

For cause of action against the Defendants, Plaintiffs respectfully show to the Court:

I.

PARTIES AND JURISDICTION: The parties to this action and the facts which establish jurisdiction of this Court are:

1. *PLAINTIFFS*:

a. Jimmie Stowe, surviving husband of Juanita Stowe, is a resident of the State of Oklahoma.

b. Glen L. Rutherford is a resident of Conway Springs, Kansas.

c. Gene W. Schneider and Phyllis S. Schneider, husband and wife, are residents of Tulsa, Oklahoma.

2. *DEFENDANTS*: The United States of America (hereafter "USA"); and Casper Weinberger, Secretary of Health, Education and Welfare of the United States of America, (hereafter "SECRETARY"). Defendant,

SECRETARY, supervises the United States Food and Drug Administration (hereafter "FDA").

3. The Plaintiffs are seeking relief under the Fifth and Fourteenth Amendments to the Constitution of the United States, under the Federal Food, Drug and Cosmetic Act, 21 USC 1/392, and the Administrative Procedures Act, 5 USC 701, Sec. 2. By reason of the arbitrary and capricious actions of the SECRETARY as hereafter set forth, the rights of Plaintiffs, under the Constitution of the United States and under the above statutes have been violated to the extent that Plaintiffs are entitled to judicial relief in this cause; and, in addition, Plaintiffs maintain this action as a class action under Rule 23, Federal Rules of Civil Procedure, as representative parties on behalf of all cancer victims, and their spouses who may be liable for the exhorbitant costs of the "acceptable, modern curative methods (surgery and radiation)" to which the legislative type order of the SECRETARY, as published in the Federal Register, have restricted cancer victims. This class is so numerous that joinder of all members is impractical, questions of law and fact and claims and defenses are common to all, and the above Plaintiffs will fairly and adequately protect the interest of the class. With this action involving constitutional rights of the Plaintiffs, and the United States of America and its Secretary of Health, Education and Welfare parties hereto, this Honorable Court has jurisdiction over the parties to and subject matter of this action.

II.

RELATIONSHIP OF PARTIES: By reason of action heretofore taken by the SECRETARY under and pursuant to 21 USC 355, a vitamin substance (B-17, also identified as Laetrile and Amygdalin) has been considered by the SECRETARY as a "new drug" within the definition of 21 USC 321(p); and the SECRETARY has, by a series of proceedings known to the SECRETARY, but unknown to Plaintiffs issued orders and regulations which preclude the dispensing of the said vitamin substance to persons suffering from cancer, upon the stated ground that the efficacy of the substance had not

adequately been proven as a cancer remedy, and its use as a segment of anti-cancer therapy could have the result of precluding persons suffering from cancer from receiving other treatments recognized by the medical profession, and the use of other drugs approved by the SECRETARY; and the United States of America, through its agents and appointed officials is now precluding the transportation in Interstate Commerce of Vitamin B-17/Laetrile to the prejudice and in violation of the constittuional rights of Plaintiffs and others included in the class represented by Plaintiffs and others included in the class represented by Plaintiffs in this class action, to purchase in interstate commerce, or otherwise, and have administered to them by medical practitioners the said Vitamin B-17.

III.

CAUSE OF ACTION: Plaintiffs state that the Plaintiff, JUANITA IRENE STOWE, was suffering from cancer of the brain and lung; and was confied to Deaconess Hospital in Oklahoma City, Oklahoma, where she and the Plaintiff, JIMMIE STOWE, were incurring extensive financial obligations for her treatment with no hope of ultimate relief. Plaintiffs state that, because of the order and regulation of the SECRETARY, the Plaintiff, JUANITA IRENE STOWE, was unable to have nurses and doctors affiliated with the hospital administer to her B-17/Laetrile, which she had in her possession, and elected to use for the purpose of creating within her body a metabolic enzymatic reaction that would expose the cancer infested trophoblast cells to the destructive force of her body's white blood cells, thus permitting natural reactions of her body to control the out-of-phase reactions of the cancerous trophoblast cells in her body. Before she was able to obtain such treatment with B-17/Laetrile, JUANITA IRENE STOWE died; and Plaintiff, JIMMIE STOWE, incurred extensive medical, hospital and burial expenses, many of which are still unpaid.

The Plaintiff, PHYLLIS S. SCHNEIDER, is now suffering from terminal cancer; and, unless she is permitted to receive Vitamin B-17/Laetrile treatments, she

faces the same fate as JUANITA STOWE. The Plaintiff, GLEN L. RUTHERFORD, has been treated with Vitamin B-17/Laetrile for approximately four (4) years, and his cancer is temporarily dormant; but, with his supply of Vitamin B-17/Laetrile blocked by the refusal of the Defendant, SECRETARY, to permit transport of Vitamin B-17/Laetrile in interstate commerce, he faces a re-occurrence and escalation of his cancer, with probably fatal results.

Plaintiffs state that the "liberty" protected by the Due Process Clause of the Fifth and Fourteenth Amendments to the Constitution of the USA would preclude the USA, acting by and through the SECRETARY, from invading the vital right of Plaintiffs to assert a freedom of choice in requesting the administration of an injection into the bodies of the said cancer victims B-17/Laetrile for the purpose of accelerating their natural metabolic reactions, so long as such election of remedy on the part of the cancer victim is taken with full knowledge of all scientific analyses presented by the SECRETARY, through the FDA. Plaintiffs further state that there has been no FDA analysis of B-17/Laetrile that would indicate lethal or even adverse effects upon the human body; but Plaintiffs and other cancer victims, present and future are denied their Constitutional right and liberty to obtain such treatment, solely by an FDA report that B-17/Laetrile had not yet been adequately proven as an effective anti-cancer therapy. With this information fully known to Plaintiffs, and available to other cancer victims, they would have a constitutional freedom of choice to request the administration of B-17/Laetrile; and an Order of this Honorable Court is sought to prevent the Defendant, SECRETARY, through the HEW and FDA, from precluding and restricting Plaintiffs' liberty, with a knowing freedom of choice, to obtain Vitamin B-17/Laetrile treatment as above set forth. Plaintiffs state that the action of the SECRETARY, in arbitrarily and capriciously, through HEW and FDA, precluding and restricting Plaintiffs' liberty of a knowing freedom of choice to obtain Vitamin B-17/Laetrile treatment as set forth above are a violation of Plaintiffs' constitutional rights as well as the constitutional rights of the entire

class of cancer victims, present and future, and such action of the SECRETARY, in the arbitrary and capricious exercise of administrative judgment, to deny dying people a freedom of choice to obtain B-17/Laetrile treatments, when a pregnant woman has been recognized as having a freedom of choice to demand an abortion, is a denial of Plaintiffs' constitutional rights including equal protection of the law, as well as denial of similar constitutional rights of other citizens of the USA.

IV.

REQUESTED RELIEF: Plaintiffs state, that by reason of the actions of SECRETARY, as above set forth, and deprivation of Plaintiffs' constitutional rights, Plaintiffs have no adequate remedy at law and are entitled to equitable relief as follows:

1. Judgment herein ordering and directing the SECRETARY to cease and desist from enforcement of order of FDA precluding the administration of Vitamin B-17/Laetrile to patients suffering from cancer.
2. In addition, and as ancillary relief, Plaintiffs are entitled to declaratory judgment under and pursuant to 28 USC 2201, as an enlargement upon the Plaintiffs remedy against the SECRETARY, upon the ground of existence of an actual controversy within the jurisdiction of this Court, not involving Federal taxes; and Plaintiffs are entitled to a declaration and adjudication that the action of the SECRETARY in denying to Plaintiffs the right to have injections and dosages of Vitamin B-17/Laetrile is an unconstitutional denial and invasion of Plaintiffs' rights and liberties, under the Constitution of the United States of America.
3. The former Plaintiff, JUANITA IRENE STOWE, passed away before she was able to assert her constitutional rights before this Honorable Court; and the Plaintiff, PHYLLIS S. SCHNEIDER, faces a similar fate. In order to assert her constitutional rights to take advantage of the therapy to which she is entitled as an American Citizen, the said Plaintiff respectfully requests an early hearing for a temporary order to permit administration

to her of B-17/Laetrile, both interveneously and orally until this cause can be tried on its merits.

WHEREFORE, Plaintiffs pray judgment herein against the USA and the SECRETARY, as follows:

1. Judgment herein ordering and directing the SECRETARY to cease and desist from enforcement of order of FDA precluding the administration of Vitamin B-17/Laetrile to patients suffering from cancer.
2. In addition, and, as ancillary relief, Plaintiffs are entitled to declaratory judgment under and pursuant to 28 USC 220K, as an enlargment upon the Plaintiffs' remedy against the SECRETARY, upon the ground of existence of an actual controversy within the jurisdiction of this Court, not involving Federal taxes; and Plaintiffs are entitled to a declaration and adjudication that the action of the SECRETARY in denying to Plaintiffs the right to have injections and dosages of Vitamin B-17/Laetrile is unconstitutional denial and invasion of Plaintiffs' rights and liberties, under the Constitution of the United States of America.
3. That the Court fix an early date for a hearing of Plaintiff, PHYLLIS S. SCHNEIDER, Application for Temporary Relief; and that Defendants be ordered to show cause why a temporary order should not be entered authorizing the administration of B-17/Laetrile to Plaintiff, PHYLLIS S. SCHNEIDER, pending further order of the Court in this cause.
4. That Plaintiffs have such further judgment and relief, as may appear just and proper.

/s/ Clyde J. Watts
CLYDE J. WATTS
Attorney for Plaintiffs

OF COUNSEL:

WATTS, LOONEY, NICHOLS,
JOHNSON & HAYES
219 Couch Drive
Oklahoma City, Oklahoma 73102
(405) 235-7641

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

No. CIV-75-0218-B

[Filed August 14, 1975]

JIMMIE STOWE, Surviving husband of JUANITA STOWE, Deceased; GLEN L. RUTHERFORD; and GENE W. SCHNEIDER and PHYLLIS S. SCHNEIDER, husband and wife, individually and on behalf of a class composed of cancer victims and their spouses, who are responsible for the costs of treatment, PLAINTIFFS

vs.

UNITED STATES OF AMERICA and CASPER WEINBERGER, Secretary of Health, Education and Welfare, DEFENDANTS

ORDER

Based upon the Findings of Fact and Conclusions of Law filed herein this day,

IT IS ORDERED, ADJUDGED AND DECREED that the defendant United States of America and defendant Casper Weinberger, Secretary of Health, Education and Welfare, his successors, and each of them and their representatives, agents, servants and employees be enjoined from preventing the plaintiff Glen L. Rutherford from purchasing and moving in interstate commerce, and having for his own personal use, not for sale, barter or to be given away to any other person an amount not in excess of a six-months' supply of Vitamin B17 or laetrile, the prescribed daily requirement being "2 pills (500 mg each) a day and 3 Wobe-Mugos enzymes a day." A six-months' supply, therefore, of each of these drugs would amount to 365 laetrile pills and 547 Wobe-Mugos enzymes.

IT IS FURTHER ORDERED, ADJUDGED AND DECREED that the plaintiff Glen L. Rutherford give advance notification to the defendants' attorney of record of the date, place and quantity of his transportation in interstate commerce of such amount of laetrile as above authorized. Such quantity shall further be declared to the immigration authorities, and custom or tax, if any, due thereon shall be paid.

IT IS FURTHER ORDERED, ADJUDGED AND DECREED that the above and foregoing Order be, and the same is hereby stayed for a period of sixty (60) days from this date.

Dated this 14th day of August, 1975.

/s/ Luther Bohanon
United States District Judge

UNITED STATES DISTRICT COURT
W.D. OKLAHOMA

No. CIV-75-0218-B

GLEN L. RUTHERFORD, PLAINTIFF, INTERVENOR

and

JIMMIE STOWE and GENE SCHNEIDER, Individually and on behalf of a class composed of cancer victims and their spouses, who are responsible for the costs of treatment, ORIGINAL PLAINTIFFS

v.

UNITED STATES OF AMERICA and CASPER WEINBERGER, Secretary of Health, Education and Welfare, DEFENDANTS

Aug. 14, 1975
As Amended Oct. 10, 1975

FINDINGS OF FACT AND CONCLUSIONS OF LAW

BOHANON, District Judge.

The case was called and the parties announced ready for trial on plaintiff's Amended Complaint insofar as it pertains to a temporary injunction, plaintiff praying that this Court order and direct the Secretary of Health, Education and Welfare (HEW), of which the Federal Drug Administration (FDA) is a branch, to desist from precluding the administration of Vitamin B17 or laetrile to patients in the United States suffering from cancer.

The plaintiffs seek relief under the Fifth Amendment to the Constitution of the United States from the provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 1-392 alleging that by reason of the arbitrary and capricious acts of the Secretary the rights of the plaintiffs, under the Constitution of the United States and under the statutes herein involved, have been violated wherein plaintiffs are entitled to judicial relief and

are entitled to maintain this action as a class action under Rule 23 Federal Rules of Civil Procedure.

Plaintiff Glen L. Rutherford testified that he became ill with cancer in the summer and fall of 1971 and that he was examined by local medical doctors who concluded that he was suffering from cancer. Thereafter he was sent to J. Walker Butin, M.D. of the Wichita Clinic, Wichita, Kansas, for examination and diagnosis.

A number of letters were written by the doctors treating Mr. Rutherford, none of which letters were written in contemplation of this legal action. Such letters which comprise Plaintiffs' Exhibit 1 are in pertinent part as follows:

On November 30, 1971, J. Walker Butin, M.D., of the Wichita Clinic, wrote to Eugene C. McCormick, M.D. of Wellington, Kansas, regarding plaintiff Rutherford:

> *"Dear Dr. McCormick:*
>
> *. . . We found the source of his bleeding on sigmoidoscopy. A large polyp is present at 15 cm. from the anal sphincter. It prolapses down and fills the lumen at this point. I was able to biopsy it and the specimen was sent to the Associated Laboratories; we should have a report in two or three days.*
>
> *My proposal is that he be seen by Dr. Bartlett here with a sigmoidoscopy to see if it might be possible to remove this polyp from below by fulguration. At the moment I think it probably is too large for anything but surgical removal, but if it is okay with you and the patient, we will schedule him to see Dr. Bartlett for his opinion.*
>
> * * * *
>
> *At the moment the arrangement is that he will call us back for the biopsy report in 72 hours, and we will arrange follow-up with Dr. Bartlett and will get his polyp out in the near future."*

Dr. Butin again wrote on December 4, 1971:

"Dear Dr. McCormick:

Here is the latest followup on Mr. Rutherford.

He was seen by Dr. Bartlett yesterday, December 3, and was advised that, because of the biopsy showing an invasive adenocarcinoma in the polyp, he should have open operation.

Consequently, he is scheduled to enter Wesley Medical Center on December 10, 1971, for preoperative colon prep and apparently will have surgery several days later, possibly on Tuesday, December 14. The lesion is at about 15 centimeters which is an area where abdominoperineal resection is sometimes necessary. However, it is our hope that he can have an anterior resection with reformation of the normal bowel continuity possible."

On February 28, 1972, Dr. Butin wrote to Dr. Price of Wellington, Kansas:

"Dear Dr. Price:

Mr. Rutherford reported to the Wichita Clinic on November 1, 1971, with a history of aching in the left upper quadrant and bloody stools. On examination, he was rather tender in the middle and left upper abdonmen, but there were no specific findings of mass or palpable organs.

Sigmoidoscopy of 15 cm revealed a large prolapsing polyp which appeared pedunculated. This was biopsied and the path report described invasive, well differentiated adenocarcinoma.

He saw Dr. Bartlett on December 3, 1971, and was scheduled to enter Wesley on December 10 for surgery. He was told that removal of the rectum might be necessary but that it would be saved, if possible. As you are well aware, he has not reported for this surgery.

* * * *

We would certainly urge Mr. Rutherford not to delay any longer than the three months, which have already been lost, in the treatment of his polyp. This should be an entirely curable lesion, if removal is performed without delay."

The plaintiff Glen L. Rutherford testified that he was tremendously upset and concerned about the prospects of surgery and the results thereof and that he went to Centro Medico Del Mar in Tijuana, Mexico, for examination and treatment shortly after the report from Dr. Butin was made to him. He stated that at Centro Medico Del Mar he was treated with Vitamin B17 or laetrile for a period of weeks and that through this treatment his condition was cured; that he has returned to his home and has been working at all times since, averaging 10 to 12 hours per day. Mr. Rutherford stated that he has no ill effects of the cancer. However, he feels that without the continued use of laetrile as diagnosed by Dr. Carlos Lopez he faces the prospect of escalation of the lethal cancer cells and thus is seeking relief in this Court for the privilege of buying laetrile for his own use and not for sale or barter to others.

Carlos Lopez, M.D., of the Centro Medico Del Mar, Tijuana, Mexico, wrote on August 8, 1974:

"Re: Glen L. Rutherford

This 57 year old white male came to us for a checkup on June 27, 1974. His past history revealed rectal bleeding in the summer of 1969. Saw a doctor at this time and was told it was diverticulitis. He was referred to Dr. Butin in November 1971. After a sigmoidoscopy they found a large polyp and a biopsy was performed. This showed invasive adenocarcinoma. Scheduled for surgery December 10, 1971, but did not show up.

Came first time to our hospital on December 21, 1971. After treatment here the bleeding had quit and we cauterized the remaining polyp. The treatment was Amygdalin i.v. (3 grams) plus proteolytic enzymes. He took home oral Bly and Wobe-Mugos enzymes.

Now he has come again for a checkup. Physical examination unremarkable . . . .

Chest X-Rays show a doubtful nodule in the left lung in the R.M.L. portion (lingula). The rest of the studies were negative. Barium enema did not show any tumors in the rectum, but showed a diverticulitis inflamation of some of them and others with fecal matter.

We asked him to continue on same dosage of B17 2 pills (500 mg each) a day and 3 Wobe-Mugos enzymes a day."

The Court is compelled to find from the testimony and the exhibits that plaintiff Glen L. Rutherford was in late 1971 suffering from invasive adenocarcinoma and that by the use of laetrile, B17 or amygdalin (all being the same drug) his condition was cured, as there is no evidence to the contrary.

The Court finds that plaintiff's Exhibit 2 is a letter from Mr. Rutherford's supplier of B17 or laetrile stating plaintiff's last order of laetrile was seized. It states that the carrier is in jail facing a $10,000 fine and five years in prison for his efforts to furnish Mr. Rutherford his 1975 supply of laetrile. The writer says that the clinic cannot be responsible and that therefore there will be no more mail orders of laetrile in the future.

The Court finds that the plaintiff Rutherford is not free to have shipped to him, nor is he free to directly purchase and bring back to the United States from Mexico quantities of laetrile for preventive treatment of his cancer. To do so would violate the law and would subject him to criminal prosecution.

21 U.S.C. § 355 provides:

"(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug."

In this connection the Court finds that laetrile has been in use for a number of years in Mexico and other nations around the world; that the FDA has by its

regulations made it impossible for the common man to have an application processed through FDA so that said agency would either approve or disapprove the drug known as laetrile. The Court finds that Congress intended by 21 U.S.C. § 355 that the FDA would on its own initiative and in good faith approve or disapprove the use of laetrile, thereby allowing the courts jurisdiction of the subject matter.

The Court finds that the FDA has abdicated its duty to make a clear determination of whether the drug laetrile should or should not be placed in commerce though the drug has been in use for many years and thousands of persons have been treated with it.

The Court finds from the record, testimony and exhibits that laetrile is not lethal in any sense of the word. It is not harmful to the human body and when used in proper amounts under proper control and supervision can effect relief from cancer disease to the satisfaction of many who are privileged to use the same.

The Court further finds from the record that the plaintiff Rutherford herein and those similarly situated have been denied this right of choice in using B17 or laetrile without just cause on the part of the Secretary of HEW and its agency FDA.

Inaction by the FDA constitutes the crux of plaintiff's procedural dilemma, and the question arises relevant to plaintiff's request for equitable relief, as to whether an interpretation or construction of § 355 authorizes such inaction and is in keeping with the Congressional intent the statute embodies. Section 355 states in part:

"(c) Within one hundred and eighty days after the filing of an application . . . the Secretary shall either—

(1) approve the application . . . or

(2) give . . . notice of an opportunity for a hearing . . . .

(d) If the Secretary finds, after due notice to the applicant . . . that (1) the investigations . . . do not

include adequate tests . . .; (2) the results . . . show that such drug is unsafe . . . or do not show that such drug is safe . . .; (3) the methods used . . . or (5) . . . there is a lack of substantial evidence that the drug will have the effect it purports . . . he shall issue an order refusing to approve the application."
(Emphasis Added)

It can be seen that the statute allows but two alternatives: the issuance of an order approving the application or the issuance of an order refusing to approve the application. The evidence does not reflect the Secretary to have done either. Without a refusal order, the plaintiff may not invoke the jurisdictional grant of § 355 giving jurisdiction to the Court of Appeals where applicant resides or the United States Court of Appeals for the District of Columbia. This section permits the United States Court of Appeals for the Tenth Circuit to take original jurisdiction.

Thus the statutory duty has not been carried out and cancer victims have thereby been placed in limbo with regard to laetrile, unable to invoke the jurisdiction of the courts. Since the Secretary has failed to act, the Court must act on behalf of this plaintiff who has been adversely affected by such failure. Congress has not legislated a statute which can be used by silence and inaction to still the clamor and demands of citizens, especially those nearly 1,000 who die each day of cancer.

Since the FDA has failed to act in contemplation of what Congress intended by § 355, the Court concludes and finds the HEW and FDA have in fact disapproved the use of laetrile and that this Court does have jurisdiction for want of action on the part of such governmental agencies.

Michael L. Culbert states in his book, *Vitamin B17*, published by Arlington House, New Rochelle, New York, at page 81:

> *"In April 1970 the Food and Drug Administration assigned IND (Investigative New Drug) application 6734 to the McNaughton Foundation, based in California, to test amygdalin-Laetrile, a move which*

> *would have given the foundation permission to obtain supplies of the 'investigational drug' and to initiate clinical studies. Then, ten days later, permission was suddenly revoked by the FDA, allegedly at the behest of the then surgeon general Jesse Steinfeld, a California physician involved in the California Medical Association ban on the compound in the 1950s. Dr. Charles C. Edwards, FDA commissioner, stated on June 9, 1970:*
>
> > *As with all 'cancer' drugs the review of the IND was expedited . . . This review was completed on April 27, 1970, 21 days from the date of receipt. The review disclosed a number of serious preclinical deficiencies.*
> >
> > *On April 28, 1970, a 10-day pretermination notice was issued detailing the deficiencies in the notice, and the sponsor was notified by wire to immediately cease clinical studies. The sponsor was allowed 10 days in which to either request a conference or to correct the deficiencies which were brought to his attention.*
> >
> > *Since the sponsor did neither, the IND was terminated on May 12, 1970.*"

The Court finds that the plaintiff Rutherford and those similarly situated are wholly without means or resources to comply with the provisions of 21 U.S.C. § 355(b) and that for the plaintiff Rutherford and those similarly situated to be denied the freedom of choice for treatment by laetrile to alleviate or cure their cancer, was and is a deprivation of life, liberty or property without due process of law guaranteed by the Fifth Amendment to the Constitution of the United States.

In *Abbott Laboratories* v. *Gardner*, 387 U.S. 136, 87 S.Ct. 1507, 18 L.Ed.2d 681 (1967) where a similar problem confronted the Courts, the Supreme Court recognized that the issue was a proper subject for judicial resolution, where a hardship from precluding Court consideration was demonstrated. Certainly hardship is revealed in this case where plaintiffs are afflicted with cancer and

are denied their choice of treatment by surgery, radiation cobalt treatments or by laetrile. The Supreme Court in the above cited case makes the following comments:

> *"The first question we consider is whether Congress by the Federal Food, Drug, and Cosmetic Act intended to forbid pre-enforcement review of this sort of regulation . . . . The question is phrased in terms of 'prohibition' rather than 'authorization' because a survey of our cases shows that judicial review of a final agency action by an aggrieved person will not be cut off unless there is persuasive reason to believe that such was the purpose of Congress. . . .*
>
> *. . . The Government relies on no explicit statutory authority for its argument that pre-enforcement review is unavailable . . . .*
>
> *. . . 'any citizen aggrieved by any order of the Secretary, who contends that the order is invalid, may test the legality of the order by bringing an injunction suit against the Secretary, or the head of the Bureau, under the general equity powers of the court.'*
>
> * * * *
>
> *This is also a case in which the impact of the regulations upon the petitioners is sufficiently direct and immediate as to render the issue appropriate for judicial review at this stage."*

In *Roe* v. *Wade*, 410 U.S. 113, 93 S.Ct. 705, 35 L.Ed.2d 147 (1973), the Court extended to a pregnant woman the right of "privacy" which included the right to demand an abortion, contrary to a state criminal statute, even though the Constitution does not explicitly mention any right of privacy. The Court, nevertheless, extended such constitutional right to a pregnant woman in the following language:

> *"This right of privacy, whether it be founded in the Fourteenth Amendment's concept of personal liberty and restrictions upon state action, as we feel it is, or, as the District Court determined, in the Ninth Amendment's reservation of rights to the people, is broad enough to encompass a woman's decision whether or not to terminate her pregnancy."*

Justice Stewart in a concurring decision commented:

> *"Several decisions of this Court make clear that freedom of personal choice in matters of marriage and family life is one of the liberties protected by the Due Process Clause of the Fourteenth Amendment."*

The Court concludes that in cases where jurisdiction is clearly shown, the Court may balance the various factors appropriate to the requested relief. Here the evidence is convincing that irreparable harm to the plaintiff overshadows the possible harm to the defendants or other interested persons. The plaintiff Rutherford's cancer is presently dormant; however, there is danger of recurrence of the cancer unless plaintiff continues to receive treatment. In addition, the plaintiff in order to have and use B17 or laetrile is subjecting himself and his agent to criminal prosecution should plaintiff contravene prohibitions set out in § 355 by making what plaintiff feels is a life versus law decision, *Continental Oil Co.* v. *Frontier Ref. Co.*, 338 F.2d 780 (C.A. 10, 1964).

The Court concludes that it has jurisdiction under 28 U.S.C. § 1337 where provision is made for jurisdiction of proceedings arising under any Act of Congress regulating commerce and where the prohibiting language of § 355 of the Pure Food and Drug Act stems from and has to do with commerce powers of the United States. It has been shown that the plaintiff here is precluded from transporting laetrile or B17 in commerce. *See Schatte* v. *International Alliances of Theatrical Stage Employees & Moving Picture Operators of U.S. and Canada*, 70 F.Supp. 1008 (D.C. Cal. 1947), *aff'd* 165 F.2d 216 (9 Cir.) *cert. denied* 334 U.S. 812, 68 S.Ct. 1018, 92 L.Ed. 1743.

The Court finds from the evidence that laetrile is not a toxic or harmful substance if used in proper dosage but is on the other hand an alternative treatment of cancer which can be used in lieu of surgery or radiation cobalt.

After plaintiff presented its evidence and rested, the Court inquired of defendant counsel if defendant had any evidence to offer and the reply was in the negative. Thereafter the following colloquy took place:

> *"MR. GELLER: On the jurisdictional issue, if the Court finds that there is no jurisdiction, the Court could, I believe, allow them to take that up on appeal. If the Court finds there is no jurisdiction, then there is no lawsuit anyway and I think that would be a final judgment.*
>
> * * * *
>
> *MR. GELLER: If the Court did grant a temporary injunction, we would take a stay and we would take it up to the Circuit as soon as possible for review by the Tenth Circuit Court of Appeals.*
>
> *THE COURT: Suppose I would enter an injunction in the nature of a permanent injunction and stay it until you could take it up on appeal.*
>
> *MR. GELLER: Assuming the Court would be found to have jurisdiction, then what the Court would in essence be doing would be saying that this drug is perfectly acceptable to be used and would be an implicit finding by the Court that this drug is effective for the use for which it is intended and perfectly safe, and I think under the state of the evidence before the Court it is not possible to make such a finding. The Government has not presented nor has it been aware of the necessity to do so in the nature of a hearing on the merits. It has been our understanding that this is temporary to allow one individual to receive this and we have attacked it solely on the jurisdictional ground."*

From all of the facts and circumstances in this case the Court concludes that proper equitable injunctive relief should be granted and a proper Order will accordingly be filed.

UNITED STATES COURT OF APPEALS
TENTH CIRCUIT

No. 75-1725

GLEN L. RUTHERFORD, PLAINTIFF INTERVENOR-APPELLEE

and

JIMMIE STOWE and GENE SCHNEIDER, Individually and on behalf of a class composed of cancer victims and their spouses, who are responsible for the cost of treatment, ORIGINAL PLAINTIFFS-APPELLEES

v.

UNITED STATES OF AMERICA and DAVID MATHEWS, Secretary of Health, Education and Welfare, DEFENDANTS-APPELLANTS

Argued and Submitted July 30, 1976

Decided Oct. 12, 1976

Before HOLLOWAY, McWILLIAMS and DOYLE, Circuit Judges.

WILLIAM E. DOYLE, Circuit Judge.

The Department of Health, Education and Welfare here seeks review and reversal of a judgment of the District Court for the Western District of Oklahoma which temporarily enjoined the Department, and particularly the Food and Drug Administration, from preventing appellee Rutherford from obtaining a supply of a controversial cancer drug called Laetrile for his own use. An order was issued on behalf of Rutherford which allowed him to purchase and transport in commerce a six months' supply of Laetrile and accompanying drugs. In the course of this order the trial court found that Laetrile was not toxic and further found that if properly administered it would "effect relief from cancer disease to the satisfaction of many who are privileged to use the same." The court also ruled that the FDA

was required under the law to approve or disapprove Laetrile as a cancer treatment and that it had neglected its duty in this regard. The judge also held that the new drug application requirements contained in the Food and Drug Act, Section 505(b), 21 U.S.C. Section 355(b), violated the Fifth Amendment due process clause in that they prescribed expensive procedures which could not be carried out by persons in the position of Rutherford.[1]

The government seeks reversal on statutory grounds:

First, that it (FDA) has no duty to approve a new drug unless a so-called new drug application is submitted to it.

Second, that it is not empowered to determine the safety and efficiency of Laetrile.

Third, that the court exceeded its authority in issuing the injunction, the effect of which was to block the enforcement of an Act of Congress without convening a three-judge court, 28 U.S.C. Sections 2282 and 2284.

We need not review the judge's ruling that Laetrile is an effective treatment for cancer or that Laetrile is not toxic or that the new drug application provision is unconstitutional. We confine ourselves to the issue whether the so-called new drug procedure constitutes, as H.E.W. contends, the only legal route that is available for testing the drug for harmfulness or harmlessness. So considered, we are of the opinion that the question whether this is a new drug presents a mixed question of fact and law which should be fully tried. As it is, the FDA's record is grossly inadequate and consists merely of a conclusory affidavit of an official of the FDA which

[1] The suit was initially brought as an individual action only by a cancer patient, Juanita Stowe, and her husband on March 12, 1975. Judge Daugherty heard and denied Mrs. Stowe's request for a preliminary injunction allowing her to obtain Laetrile on March 14, 1975. Mrs. Stowe subsequently died. An amended complaint was filed June 30, 1975 by two other cancer patients, Rutherford and Phyllis Schneider, and Mrs. Schneider's husband, on behalf of cancer victims and their spouses. Mrs. Schneider died before the hearing on a preliminary injunction held July 11 and 18, 1975, before Judge Bohanon. There has been no certification of the lawsuit as a class action.

in effect declares that it is a new drug because the FDA says it is and thus is subject to all of the statutory vagaries of such a designation.

I.

As we view it, the reason that the Food and Drug Administration is anxious to classify Laetrile as a new drug is so as to bring it within the new drug certification procedures of the Food, Drug and Cosmetics Act. Section 505(a) of the Act, 21 U.S.C. Section 355(a). This provision bars the introduction into interstate commerce of a new drug without an approved new drug application having been filed pursuant to the Act just cited. The Secretary is required to review the application within a specified period on the criteria of safety and effectiveness as demonstrated by "adequate and well-controlled investigations." Such an application is reviewable directly in the court of appeals. The plaintiff-appellee's position on this is that Laetrile escapes the clutches of this Act by being a food rather than a drug, or even if it is a drug it is not a new drug.

A.

It is unnecessary to linger and dwell on the subject whether it is a food or a drug inasmuch as this is not determinative. Appellee argues that it is in the nature of a diet supplement or a vitamin, but the cases recognize that even if a substance is also a food it may be subjected to the requirements of the Act if it is used in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals.[2] Intended use is an important aspect in the determination whether it is a

[2] *Kordell* v. *United States*, 335 U.S. 345, 69 S.Ct. 106, 93 L.Ed. 52 (1948) (mixture of minerals, vitamins, and herbs); *Seven Cases* v. *United States*, 239 U.S. 510, 518, 36 S.Ct. 190, 60 L.Ed. 411 (1916) (alcoholic solution); *United States* v. *Allan Drug Corp.*, 357 F.2d 713 (10th Cir.), *cert. denied*, 385 U.S. 899, 87 S.Ct. 203, 17 L.Ed.2d 131 (1966) (vitamin supplements offered as acne cure); *United States* v. *Millpax, Inc.*, 313 F.2d 152, 153-54 (7th Cir. 1963), *cert. denied*, 373 U.S. 903, 83 S.Ct. 1291, 10 L.Ed.2d 198 (1963) ("iron tonic"); *United States* v. *250 Jars of U.S. Fancy Pure Honey*, 218 F.Supp. 208 (E.D. Mich 1963), *aff'd*, 344 F.2d 288 (6th Cir. 1965) (honey sold for therapeutic purposes).

drug. *See Hanson* v. *United States*, 417 F.Supp. 30 (D. Minn. 1976).

Unquestionably Laetrile is *intended* at least as a treatment for cancer, so the likelihood that Rutherford can demonstrate that it is not a drug at all appears slim. Hence if this were the only issue to sustain the injunction it would be unnecessary to proceed further.

B.

THE QUESTION WHETHER LAETRILE IS A NEW DRUG

Rutherford vigorously argues that even if it is a drug it is not a new one, and therefore, it is exempt from the thicket which results from seeking to comply with Section 505(a) of the Act. A new drug is defined in Section 201(p) of the Act, 21 U.S.C. Section 321(p) as follows:

> (p) The term "new drug" means—
>
> (1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or
>
> (2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to

> a material extent or for a material time under such conditions.

Essentially, then, a new drug is a substance which may or may not be generally recognized by scientific experts as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling thereof. A substance is not regarded as a new drug if at any time prior to 1962, the date of the New Drug Amendment in question, it was subject to the Act of June 30, 1906, as amended. The effect of this definition is that there is a twofold grandfather clause exemption which is capable of removing Laetrile from the new drug category even if it is not recognized by the experts as being safe and effective which, by the way, does not say that it is unsafe and ineffective. The first of these grandfather exemptions comes from transitional provisions attached to the 1962 Amendments to the Food, Drug and Cosmetic Act of 1938. The second grandfather exemption arises from provisions attached to the 1938 Act when it superseded the original Food and Drug Act of 1906.

1. Whether the Transitional Provisions Between the 1938 and 1962 Acts Applies

Prior to the 1962 Amendment the only prerequisite for a drug to avoid classification as a new drug was recognition that it was safe. But the 1962 Amendment added the requirement of "effectiveness." *See* Act of October 10, 1962, Pub. L. 87-781, Section 102(a)(1). One of the transitional provisions enacted in 1962 was as follows:

> In the case of any drug which, on the day immediately preceding the enactment date (October 10, 1962), (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201(p) of the basic Act as then in force (21 U.S.C. Section 321(p)), and (C) was not covered by an effective (new drug) application under 505 of that Act (21 U.S.C. Section 355), the amendments to section 201(p) made by this Act shall not apply to such drug when intended solely for use

> under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day. Pub. L. 87-781, Section 107(c)(4), *reprinted at* 21 U.S.C. Section 321 *note.*

The effect of this is that if on October 9, 1962, Laetrile was "marketed before 1962 for exactly the same uses for which it is presently being sold and was generally recognized by qualified experts as safe for those uses, it is exempt under this grandfather clause from the test of general recognition by experts as being both safe and *effective* for its claimed uses." *Tyler Pharmacal Distributors, Inc.* v. *United States Dep't of HEW*, 408 F.2d 95, 99 (7th Cir. 1969). *See also United States* v. *Allan Drug Corp.*, 357 F.2d 713, 717 (10th Cir.), *cert. denied*, 385 U.S. 899, 87 S.Ct. 203, 17 L.Ed.2d 131 (1966). The present record does not reveal how Laetrile was marketed before the passage of the 1962 Amendment nor does it tell us whether it was recognized as safe. We are mindful, of course, that the cause was not tried on its merits and hence these questions were not considered on preliminary injunction. They should, however, be taken up when the cause is remanded.

2. Whether the Other Transitional Provision as Between the 1906 and 1938 Acts Applies

In essence this exemption provides that a drug not recognized by qualified experts as "safe and effective"

> shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter (the 1938 Act) it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use.

21 U.S.C. Section 321(p)(1).

The effect of this above quoted provision is to exempt from the new drug classification any drug which was marketed before the Food, Drug and Cosmetic Act of 1938 was enacted and which was covered by the predecessor Act, that is, the Food and Drugs Act of 1906 (as

long as the prescribed conditions for its use are unchanged).[3]

The 1906 Act covered all substances which were recognized or used as drugs at that time. Its wide coverage is apparent from its language:

> all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation or prevention of disease of either men or other animals.
>
> Act of June 30, 1906, c. 3915 Section 6, 34 Stat. 769.

Under the second grandfather clause which is quoted above, a drug may escape the "new drug" machinery if it was marketed or officially recognized as a drug at any time before June 25, 1938, but after June 30, 1906. So if Laetrile was marketed or officially recognized as a cancer drug it would not have to be subjected to the instrumentalities which exist for new drugs under the 1962 Amendments even though it is not generally recognized as safe or effective.[4]

---

[3] *See Weinberger* v. *Hynson, Westcott and Dunning, Inc.*, 412 U.S. 609, 634, 93 S.Ct. 2469, 37 L.Ed.2d 207 (1973).

[4] We do not wish to convey that Laetrile could be marketed if it was found to be toxic or otherwise harmful, for even if Laetrile is not a "new drug" it is a drug subject to the prohibitions of Section 301 of the Act, 21 U.S.C. Section 331(a), and this provision makes unlawful "The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." A drug is "misbranded" if "it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." Section 502(j) of the Act, 21 U.S.C. Section 352(j).

So, even though the drug is grandfathered it may still be excluded as dangerous to health. The difference between unsafe and dangerous is not great. It might be judged in accordance with scientific viewpoints as of different dates. Thus the Section 502(j) standard would look to the current assessments of safety.

Our reading of this second grandfather clause is in accord with the transitional provision of the 1962 Amendments, *supra*, which

II.

SUMMARY OF REMAINING QUESTIONS

From what we have said above there remain some questions to be determined. These are:

(1) Was Laetrile marketed on October 9, 1962, as a cancer drug and was it then generally recognized as "safe?" [5]

(2) Was Laetrile recognized or used as a cancer drug under the same conditions of present use during the period when the Food and Drugs Act of 1906 was in effect, June 30, 1906 to June 25, 1938?

If the answer to either of these is "yes," Laetrile would be exempt as a "new drug" under the Food, Drug and Cosmetic Act. We regard these questions as substantial, difficult and doubtful so as to support the granting of a preliminary injunction.

The FDA has argued that they have not issued any regulation or rule which specifically or positively forbids the administration of Laetrile. This is true. However, the FDA has made an administrative determination that Laetrile is a new drug and this places the plaintiff in a position in which he has to admit that it is a new drug in order to get the FDA to move. As a result he could not be heard to say that they have not effectively stymied the use of this drug. The FDA has

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exempts from new drug status any drug "not a new drug as defined by section 201(p) of the basic Act then in force." P. Law 87-781, Section 107(c)(4)(B).

[5] The FDA argues that a drug offered for use in a life-threatening disease that is not "effective" is thereby not "safe" either. Thus even under the pre-1962 law Laetrile would have to satisfy effectiveness criteria. This argument may lose its force in the case of a terminally-ill patient or in the case of a patient suffering from a disease for which there are in fact no "effective" remedies. Compare *Duvoric* v. *Richardson*, 479 F.2d 242 (7th Cir.), *cert. denied*, 414 U.S. 944, 94 S.Ct. 232, 38 L.Ed.2d 168 (1973). *See also CIBA* v. *Weinberger*, 412 U.S. 640, 660 n.2, 93 S.Ct. 2495, 37 L.Ed.2d 230 (1973). In any case, this argument should be considered in the first instance in the further proceedings in this matter; the issue is not before us for resolution.

done this without citing any facts whatsoever, merely a conclusion, and this is the kind of declaratory order that was before the Court in *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 625-27, 93 S.Ct. 2469, 37 L.Ed.2d 207 (1973). There the Court upheld the FDA's power to declare that a substance is a "new drug" under the Act, but also held that an order of this kind is reviewable by a district court. 412 U.S. at 609, 93 S.Ct. 2469. In view of the dearth of evidence in support of the FDA's determination, it was entirely proper for the trial court to entertain this case.

From what has been said it is obvious that we are not in agreement with the trial court's opinion that the FDA has to approve or disapprove any new drug even in the absence of an application that satisfies the statutory mandate. As we have noted, Section 505(b) of the Act specifically requires the filing of a new application by the proponent of a new drug. The FDA simply rules on the application as submitted.[6] Congress in writing Section 505(b) was relying on the ability and willingness of the pharmaceutical companies to present new drugs. It follows that the FDA was not compelled to pursue this new drug procedure in the Laetrile situation in the absence of an application. *See Rutherford* v. *American Medical Ass'n*, 379 F.2d 641 (7th Cir. (1967), *cert. denied*, 389 U.S. 1043, 88 S.Ct. 787, 19 L.Ed.2d 835 (1968) (no FDA duty to initiate approval procedures for Krebiozen).

We are unable, however, to see how the FDA can escape the obligation of producing an administrative record

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[6] *See* H.R. Rep. No. 2139, 75th Cong., 3d Sess. (April 14, 1938) at 9:

> This provision (Section 505) will not put the Federal Government into the business of developing new drugs, nor will it require the Government to duplicate laboratory and clinical tests made by responsible manufacturers. The provision merely sets up a method for the authoritative review of the manufacturer's tests and will not unreasonably delay the introduction of new drugs in the market. It provides for court review of the decisions of the administrative agency adverse to the manufacturer.

See also H.R. Rep. No. 2464, 87th Cong., 2d Sess. (September 22, 1963) at 3.

to support its determination of the first and more fundamental issue that Laetrile is a *new* drug, for it is not a new drug merely because they say it is. Moreover, such a conclusory ruling precludes effective review under 5 U.S.C. Section 706(2). *Cf. Weinberger* v. *Hynson, Westcott & Dunning, Inc., supra,* which holds the new drug decision by way of 5 U.S.C. Section 554(e) to be reviewable in a district court. To support its determination the FDA in the case at bar would have to present substantial evidence to support the proposition that Laetrile is not generally recognized among qualified experts as "safe and effective," and that Laetrile is not grandfathered by either of the exemptions discussed above.

It seems doubtful that the FDA has in fact developed an administrative record adequate under 5 U.S.C. Section 554(c) and hence there is probably nothing which is presently available for a court to review. Nothing in the record suggests that the FDA has dealt with Laetrile in a rule-making proceeding under Section 701 of the Act, 21 U.S.C. Section 371. *Compare National Nutritional Foods Ass'n* v. *Weinberger,* 512 F.2d 688 (2d Cir. 1975). Hence, if this is true the appropriate procedure for the district court is to remand the case back to the FDA for proceedings adequate to develop a record supportive of the agency's determination; the proceedings should give Laetrile proponents an opportunity to express their views. This is a result which is also supported by the Supreme Court decision in *Weinberger* v. *Bentex Pharmaceuticals,* 412 U.S. 645, 93 S.Ct. 2488, 37 L.Ed.2d 235 (1973). There the district court faced with a similar problem referred the matter to the FDA for initial determination. *See* 412 U.S. at 652-54, 93 S.Ct. 2488. The question whether the drug is to be recognized as "safe and effective" or was "grandfathered in" are "the kinds of issues peculiarly suited to initial determination by the FDA." *Id.* at 653, 93 S.Ct. at 2494.

It seems obvious that there cannot be a court review unless there is a decent record made. We see no need to consider the constitutional issues which were cited by the district court nor do we regard the convening of a three-judge court to be necessary. The district court's

injunction can continue in effect pursuant to 5 U.S.C. Section 705.

We conclude that the preliminary injunction granted by the district court in this case should be and the same is upheld. At the same time, the cause is remanded for further proceedings consistent with the views expressed herein.

McWILLIAMS, Circuit Judge (dissenting).

I respectfully dissent and would vacate the judgment and order of the trial court. The judgment and order of the trial court enjoined the Secretary and his representatives "from preventing the plaintiff Glen L. Rutherford from purchasing and moving in interstate commerce, and having for his own personal use, not for sale, barter or to be given away to any other person an amount not in excess of six-months' supply of Vitamin B17 or laetrile, ..." That, as I understand it, was the extent of the judgment and order here complained of. In my view such injunctive order was improvidently entered and on appeal should be vacated.

UNITED STATES DISTRICT COURT
W.D. OKLAHOMA

No. CIV-75-0218-B

GLEN L. RUTHERFORD, ET AL., PLAINTIFFS

v.

UNITED STATES OF AMERICA, ET AL., DEFENDANTS

Jan. 4, 1977

MEMORANDUM OPINION AND ORDER

BOHANON, District Judge.

On December 30, 1976, this matter came on for pretrial conference, the plaintiffs appearing by their attorneys Kenneth Coe and Burton J. Johnson, Oklahoma City, Okl., and the defendants appearing by William S. Price, Asst. U.S. Atty., Oklahoma City, Okl., and Jay H. Geller, Associate Chief Counsel, Food and Drug Div., Dept. of Health, Education and Welfare, Los Angeles, Cal.

The United States Court of Appeals for the Tenth Circuit in its Opinion filed October 12, 1976, in this case stated in part:

> "We are unable . . . to see how the FDA can escape the obligation of producing an administrative record to support its determination of the first and more fundamental issue that Laetrile is a new drug, for it is not a new drug merely because they say it is. . . .
>
> It seems doubtful that the FDA has in fact developed an administrative record adequate under 5 U.S.C. Section 554(c) and hence there is probably nothing which is presently available for a court to review. Nothing in the record suggests that the FDA has dealt with Laetrile in a rule-making proceeding under Section 701 of the Act, 21 U.S.C. Section 371. . . . Hence, if this is true the appropriate procedure for the district court is to remand the case back to the FDA for proceedings adequate to develop a record supportive of the agency's determination; the proceedings should give Laetrile proponents an opportunity to express their views. This is a result which is also supported by the Supreme Court decision in *Weinberger* v. *Bentex Pharmaceuticals*, 412 U.S. 645, 93 S.Ct. 2488, 37 L.Ed.2d 235 (1973). There the district court faced with a similar problem referred the matter to the FDA for initial determination. See 412 U.S. at 652-54, 93 S.Ct. 2488. The question whether the drug is to be recognized as 'safe and effective' or was 'grandfathered in' are 'the kinds of issues peculiarly suited to initial determination by the FDA.' Id. at 653, 93 S.Ct. at 2494."

Subsequent to the Circuit Court's remand to this Court, counsel for the defendants admitted in open court that the FDA, in determining Laetrile * to be a new drug, had failed to create an administrative record consonant with the procedures outlined in the Administrative Procedure Act or in accordance with the rule-making procedure outlined in the Food, Drug and Cosmetic Act at 21 U.S.C. § 371. In so doing the FDA has left little to be reviewed beyond its bare determination. Under such circumstances there would be much injustice in sustaining the FDA's unsupported conclusion while, on remand, it sought ex post facto to muster evidence in support of such conclusion.

Viewing the agency's description of Laetrile as a "new drug," from the standpoint of the judicial review standards outlined at 5 U.S.C. § 706, the Court would be compelled to find such determination to be "unsupported by substantial evidence," and to conclude that the agency

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* The Court finds from the record that Laetrile, Amygdalin and Vitamin B-17 are all one in the same, and the term Laetrile will be used to represent all three.

had failed to comply with its burden of proof in this matter.

In the above-quoted Opinion, the Circuit Court emphasizes that Laetrile is not to be considered a "new drug" under the law merely because the FDA has said so, but rather that said determination must be supported by substantial evidence. The statutory presumption in favor of administrative determinations is based on the premise that such determinations are presumed to be supported by substantial evidence until a reviewing court has determined otherwise. Such presumption was overcome when FDA counsel admitted that no competent administrative record had ever been developed in support of the agency's determination. As a matter of law then, such determination is not supported by substantial evidence and cannot be sustained. *Nickol* v. *United States*, 501 F.2d 1389 (10th Cir. 1974); *Heber Valley Milk Co.* v. *Butz*, 503 F.2d 96 (10th Cir. 1974); *Bailey* v. *Weinberger*, 380 F.Supp. 863 (D.C. Kan. 1974).

Having ascertained, during the December 30, 1976, hearing, that a competent administrative record did not exist, the Court then requested that the FDA make available to the Court the written basis for the agency's determination with regard to Laetrile, no matter how casual or unstructured its form or content might be; whereupon the Court was advised that no such rationale existed in any form. Clearly, federal agencies may not rule by fiat invoking only some unexplained application of their own expertise in defense of policy decisions they have made. *Chemical Leaman Tank Lines, Inc.* v. *United States*, 368 F.Supp. 925 (D.C. Del. 1973). Based on the complete absence of any evidence tending to establish a rational basis for the agency's determination, the Court would also be compelled to find, in applying the standards of 5 U.S.C. § 706, that the agency's determination was "arbitrary, capricious," and represented "an abuse of discretion," and that it should also be overturned for these additional reasons.

In consideration of the fact, however, that the lack of an administrative record precludes judicial review at this time in any meaningful sense, and in order to grant

both sides an opportunity to fully prepare and present their respective points of view, and consistent with the Circuit Court Opinion in this matter, the Court has determined that this case should be remanded to the FDA so that an administrative record can be constructed and a meaningful judicial review subsequently held. In view, however, of the complete absence of any good-faith agency record in support of its position in this case, as the record here is not merely incomplete, but virtually nonexistent; and in appreciation of the fact that depriving a terminally ill cancer patient of a substance he finds therapeutic, whether such benefit is physical or psychological, creates the very real risk that irreparable injury might be sustained.

IT IS HEREBY ORDERED, pursuant to 5 U.S.C. § 705, that while this case is on remand to the FDA, and until such time as the FDA proffers to the Court an administrative record containing substantial evidence in support of its determination that Laetrile is a "new drug" under the terms of the relevant statute, such determination is held to be without force or effect as to the plaintiff class in this case, and defendant FDA is hereby enjoined and restrained from preventing plaintiffs' importation or interstate transportation of Laetrile for purposes of their own consumption under the terms of the Food and Drug Act, including § 505(a) of the Act, 21 U.S.C. § 355(a).

IT IS FURTHER ORDERED that on remand an administrative record shall be developed within 120 days from the date hereof, and a copy of such record and administrative determinations resulting therefrom shall be filed with the Clerk of this Court and the plaintiffs within 30 days thereafter.

Such administrative hearing should be concerned with the issue of whether Laetrile is exempt from the "new drug" application requirements of the Food and Drug Act, § 505(b), 21 U.S.C. § 355(b), by virtue of the "grandfather" clauses, and also with the issue of whether Laetrile is "safe and effective," as set out in the Circuit Court Opinion.

The plaintiffs herein have moved this Court for an Order directing the FDA to hear testimony and evidence of Dr. Dean Burk, Washington, D.C., and Dr. Ernest Krebs, Jr., San Francisco, California, as experts in their field, and also evidence and testimony of Mike Culbert, Edward Griffin and Mike Spencer, as research historians. This Court is without authority to enter such an Order; however, the Court believes that the FDA might desire to invite these persons to participate in the administrative proceedings and to receive into evidence their views with reference to the history and safety and effectiveness of Laetrile.

Pursuant to the request of the plaintiffs and based upon the pleadings and evidence in this case, it is hereby determined that this suit meets the class action requirements of Rule 23, Federal Rules of Civil Procedure, and therefore,

IT IS FURTHER ORDERED that this suit shall be certified and hereafter treated as a class action.

UNITED STATES DISTRICT COURT
W.D. OKLAHOMA

No. CIV-75-0218-B

GLEN L. RUTHERFORD, Individually and on behalf of a class composed of terminally ill cancer patients,
PLAINTIFFS

v.

UNITED STATES OF AMERICA, ET AL., DEFENDANTS

April 8, 1977

MEMORANDUM OPINION

BOHANON, District Judge.

This cause came before the Court Friday, March 18, 1977, upon plaintiffs' "Application to Clarify Plaintiff Class" in the above-captioned class action. Plaintiffs requested that the Court enter Orders certifying the plaintiff class as including "all victims of cancer and their spouses who are responsible for the cost of treatment," and declaring as members of the plaintiff class all persons certified by a physician as having cancer. Defendants argued that plaintiff does not represent a class within the meaning of Rule 23 of the Federal Rules of Civil Procedure, that certification, in any event, should be limited to terminal cancer patients, that the FDA was within the scope of its authority in banning the importation and interstate transportation of laetrile, and that consequently the FDA should not be enjoined from preventing the use of laetrile.

Three basic issues emerge from the March 18, hearing and the evidence, arguments and submitted briefs.

The Class Action Issue

Plaintiffs seek class certification in terms detailed above. Defendants oppose certification, asserting "that

the class plaintiffs purport to represent is "too ill-defined and ephemeral in makeup' to render its members 'capable of definite identification,' " and arguing that, at most, certification should encompass only terminal cancer patients.

The class action was an invention of equity, mothered by the practical necessity of providing a procedural device so that mere numbers would not disable large groups of individuals, united in interest, from enforcing their equitable rights. *Montgomery Ward & Co.* v. *Langer*, 168 F.2d 182, 187 (8th Cir. 1948). As a function of equity, it must be invoked and applied only in accordance with basic principles of fairness and reason. Under federal law, precepts of class action theory are delineated in Rule 23 of the Federal Rules of Civil Procedure.

Rule 23 possesses as its basic objectives the efficient resolution of the claims of many individuals in a single action, the elimination of repetitious litigation and possibly inconsistent adjudications involving requests for similar relief, and the establishment of an effective procedure for those whose economic position is such that it is unrealistic to expect them to seek to vindicate their rights in separate lawsuits. *Federal Practice and Procedure* § 1754, Wright and Miller.

Having carefully reviewed the facts and circumstances of this case, the applicable case law, and the requirements of Rule 23, the Court is persuaded it is appropriate to administer this matter as a class action.

In so deciding the Court has necessarily determined that plaintiff class is so numerous as to render joinder impracticable, that there are questions of law and fact common to the members of the class, that the claims of the representative plaintiffs are typical of the claims of the entire class, and that the representative plaintiffs will fairly and adequately protect the interests of the class. Additionally, the Court has concluded that defendants have acted on grounds generally applicable to the class in a way that renders injunctive relief proper. Rule 23, Federal Rules of Civil Procedure.

Although not specifically mentioned in Rule 23, an essential prerequisite of an action thereunder is that there must be a "class." *Weisman* v. *MCA, Inc.*, 45 F.R.D.

258 (D. Del. 1968). Whether a class exists is a fact question to be resolved in each case. *Clark* v. *Thompson*, 206 F.Supp. 539 (D. Miss. 1962). Rule 23 is to be construed liberally, and the class does not have to be so readily ascertainable that every potential member can be identified at the outset. *Carpenter* v. *Davis*, 424 F.2d 257 (5th Cir. 1970). Only the general outlines of the membership of the class must be determinable initially. *Berman* v. *Narragansett Racing Assn., Inc.*, 414 F.2d 311 (1st Cir. 1969). The requirement that there be a class will be deemed satisfied if class identification is sufficiently definite so that it is administratively feasible for the Court to determine whether a particular person is a member. *See Federal Practice and Procedure*, § 1760, Wright and Miller and cites therein.

Based on the evidence and arguments introduced since this case's inception, and to expedite administration of the Court's Order of January 4, 1977, plaintiff class is hereby certified as encompassing all "terminally ill cancer patients." The phrase "terminally ill cancer patient" refers to anyone who, in affidavit form as hereafter described, is declared by a practicing physician (M.D.) to be terminally ill.

Such affidavit shall include the following:

1. that there is histologic evidence of a rapidly progressive malignancy in the patient possessive of a high and predictable mortality rate; and

2. (a) that further orthodox treatment would not reasonably be expected to benefit the patient; or

   (b) that laetrile will be administered only in conjunction with established and recognized forms of cancer treatment; or

   (c) that the patient has made a knowing and intelligent election to take laetrile after being fully apprised of the full range of recognized treatments available and of the fact that laetrile is considered by most cancer experts to be of no value in combatting the disease.

Defendants assert that early diagnosis and prompt treatment are critical in the management of cancer and that needless and untimely deaths will occur if laetrile is used in preference to established methods of cancer treatment. Such arguments have little applicability to that fraction of cancer patients whose lives orthodox medical science professes no capacity to preserve. To speak of laetrile as being "unsafe" for these people is bizarre. Additionally, it is connotative of a paternalism incompatible with this nation's philosophy as to the proper relationship between the government and the citizenry.

Rule 23 is designed to avoid a multiplicity of lawsuits while protecting the substantive rights of plaintiffs and defendants. *In Re Four Seasons Securities Laws Litigation*, 63 F.R.D. 422 (W.D. Okl. 1974). The salient issues in this case are such that defendants' position is in no way prejudiced by class action treatment; instead, defendants are saved the time and expense of defending a multitude of suits. At the same time, such treatment affords immeasurable benefits to the plaintiff class. Requiring litigation of protracted and expensive individual lawsuits would effectively serve to deny many terminal cancer patients the opportunity to have their claims adjudicated. Their disease has often left them with limited funds, and made time an even more precious commodity. It appears to the Court that ignoring the advantages of class action disposition of this case would evidence an indifference to judicial economy and the general spirit of the class action concept.

The question of whether to allow a suit to proceed as a class action is one primarily for the determination of the trial judge, and if he applies the correct criteria to the facts of the case, the decision should be considered to be within his discretion. *Gold Strike Stamp Company* v. *Christensen*, 436 F.2d 791 (10th Cir. 1970).

In cases such as this, where the ultimate effectiveness of a federal remedy may depend in large measure on the applicability of the class action device, all judicial discretion should be directed toward allowing the class action. *Esplin* v. *Hirschi*, 402 F.2d 94 (10th Cir. 1968).

Defendants urge that many cancer patients have no interest in the use of laetrile. The issue before this Court is not the wisdom of using Laetrile, but rather the right of cancer patients to do so if they choose. It is not fatal to the maintenance of a class action that some members of the class might prefer not to have violations of their rights remedied. *Leisner* v. *New York Telephone Company*, 358 F.Supp. 359, 372 (S.D. N.Y. 1973); *Norwalk Core* v. *Norwalk Redevelopment Agency*, 395 F.2d 920, 937 (2nd Cir. 1968). The rights of patients unimpressed by laetrile's alleged therapeutic qualities are in no way prejudiced by this decision. Such persons must be as free to disregard laetrile as are their fellows to invoke it.

Further consideration of the appropriate bounds of the certified class is possible since the Court always has the authority to change class designations should developments so require. *Guarantee Ins. Agcy. Co.* v. *Mid-Continental Rlty. Corp.*, 57 F.R.D. 555 (N.D. Ill. 1972); *Esplin* v. *Hirschi*, *supra* at 99.

The Issue of Laetrile as a New Drug

This Court makes no determination on the limited evidence before it as to laetrile's ability to combat the ravages of cancer. Defendants have introduced evidence tending to establish the general opposition of medical authority in this country to the use of laetrile. Contrarily, the Court is aware of instances of patients and physicians in various parts of the country emphasizing personal experiences with laetrile's ability to counter aspects of the disease's manifestations and discomforts. Regardless, such issue is not before the Court, and the Court is cognizant that it possesses "neither the facilities nor the expertise" to independently determine the drug's therapeutic value. *Tutoki* v. *Celebrezze*, 375 F.2d 105, 107 (7th Cir. 1967).

It is unlawful to introduce any "new drug" into interstate commerce previous to the FDA's approval of a "new drug application" (NDA) establishing such drug as "safe" and "effective" for its intended use. The FDA has banned the importation and interstate shipment of

laetrile on grounds that an NDA on its behalf has neither been filed nor approved.

In support of its position that plaintiffs are entitled to no substantive relief, defendants urge, *inter alia*, that the initial determination of the safety and efficacy of a "new drug" is the responsibility of the FDA, that FDA has no duty to approve a "new drug" in the absence of an NDA, and that the administrative procedures applicable to new drugs and outlined in the Federal Food, Drug and Cosmetic Act must be exhausted before a court has jurisdiction. These arguments are only relevant if the premise is accepted that laetrile is, in fact, a "new drug."

It is clearly established that FDA has power to determine whether a particular drug requires an approved NDA in order to be sold to the public. *Weinberger* v. *Hynson, Westcott & Dunning*, 412 U.S. 609, 624, 93 S.Ct. 2469, 37 L.Ed.2d 207 (1973). Its determination that a product is a "new drug" is, of course, reviewable. *Weinberger* v. *Hynson, supra*, at 627, 93 S.Ct. 2469. FDA does not have unbridled discretion to do what it pleases. Its procedures must satisfy the rudiments of fair play. *Weinberger* v. *Hynson, supra.* Where FDA declares a "new drug" where no NDA is in effect and no manufacturer is submitting an NDA, such declaration is reviewable by the district court under the Administrative Procedure Act, 5 U.S.C. § 701 et seq.; *Weinberger* v. *Hynson, supra.*

In an opinion in this same case, *Rutherford* v. *United States*, 542 F.2d 1137, 1143 (10th Cir. 1976), the Circuit Court held that FDA could not escape the obligation of producing an administrative record to support its determination that laetrile is a new drug, noting that "it is not a new drug merely because they [FDA] say it is." The Court further observed that based on the record in the case it appeared doubtful that FDA had in fact developed such an administrative record, and added that "to support its determination, FDA in the case at bar . . . would have to present *substantial evidence* to support the proposition that laetrile is not generally recognized among qualified experts as 'safe and effective' and

that laetrile is not grandfathered by either of the exemptions discussed above." (emphasis supplied)

As to the "grandfather clauses" the Circuit Court specifically found that if laetrile were either marketed as a cancer drug between 1938 and 1962 and recognized as safe, or if used as a cancer drug between 1906 and 1938 under the same conditions as presently used, it is exempt from being classified as a "new drug" by virtue of definitions contained in the Federal Food, Drug and Cosmetic Act. *Rutherford* v. *United States* (10th Cir.) *supra* at 1141.

Defendants recognize in their submitted brief that: "With respect to the grandfather clause of the 1962 amendments, the test generally is whether Laetrile was 'marketed before 1962 for exactly the same uses for which it is presently being sold and was generally recognized as safe for those uses.' *Tyler Pharmacal Distributors, Inc.* v. *United States Department of Health, Education and Welfare*, 408 F.2d 95, 99 (7th Cir. 1969)."

Nonetheless, FDA contends that if laetrile were marketed prior to 1962 it must still be shown to have been "effective" as well as "safe" if employed in the treatment of "a life-threatening disease."[1] *Durovic* v. *Richardson*, 479 F.2d 242 (7th Cir. 1973). The Supreme Court in *Weinberger* v. *Hynson*, *supra*, stated that "the 1962 amendments [of the Food, Drug and Cosmetic Act] for the first time gave FDA power to scrutinize and evaluate drugs for effectiveness as well as safety." 412 U.S. at 630, 93 S.Ct. at 2483. In any event, the case relied upon by FDA is clearly distinguishable from the case at bar. In *Durovic* v. *Richardson*, *supra*, the Court held that "(a)ny delay in the institution of effective therapy (e.g., radiation, surgery, effective chemotherapy) caused by the use of an ineffective drug allows the disease to pro-

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[1] "The FDA argues that a drug offered for use in a life-threatening disease that is not 'effective' is thereby not 'safe' either. Thus even under the pre-1962 law Laetrile would have to satisfy effectiveness criteria. This argument may lose its force in the case of a terminally-ill patient or in the case of a patient suffering from a disease for which there are in fact no 'effective' remedies." *Rutherford* v. *United States* (10th Cir. 1976) *supra*, note 5 at 1142.

gress beyond control. Delay means almost certain death." Significantly, in the present case plaintiff class is comprised of persons already determined to be terminally ill. Adopting FDA's rationale would mean that an individual suffering from a life-threatening disease for which there exists no known effective treatment would not lawfully be entitled to any treatment at all since no drug could be deemed "generally recognized as effective" in such a situation.

Congress undoubtedly possesses the authority to proscribe drugs it considers dangerous to the public welfare. *Weinberger* v. *Hynson, supra* at 622, 93 S.Ct. 2469. The record in this case does not necessarily disclose any such Congressional intent as to laetrile. The FDA is not empowered to enforce its convictions concerning laetrile on the basis of its congressional mandate to monitor the introduction of "new drugs" into our society, if in fact laetrile has been used for decades in the treatment of cancer, and without ill effect. As implicitly recognized in *Rutherford* v. *United States*, (10th Cir. 1976) *supra*, the issue of the efficacy of laetrile is, at most, of secondary importance in this case. The legality of FDA's ban on laetrile is under attack on the theory that FDA arbitrarily and without sufficient basis in fact characterized laetrile as a "new drug;" so far FDA has presented little, if any, evidence to combat that allegation.

The Issue of Injunctive Relief

On August 14, 1975, this Court enjoined defendants from preventing the use of laetrile by the then named plaintiff in this action. Such injunction was subsequently upheld on appeal, the Circuit Court determining that the issues raised by FDA's classification of laetrile as a "new drug" were sufficiently "substantial, difficult and doubtful so as to support the granting of a preliminary injunction," and the case was remanded for further proceedings. *Rutherford* v. *United States*, (10th Cir. 1976), *supra*, at 1142. Thus the issue of this Court's jurisdiction to enter such an injunction has already been disposed of on appeal.

On January 4, 1977, this Court entered an Order remanding the case to FDA for development of a proper administrative record, and directing that "until such time as the FDA proffers to the Court an administrative record containing substantial evidence in support of its determination that laetrile is a 'new drug' under the terms of the relevant statute, such determination is held to be without force or effect as to the plaintiff class in this case, and defendant FDA is hereby enjoined and restrained from preventing plaintiff's importation or interstate transportation of laetrile for purposes of their own consumption under the terms of the Food and Drug Act, including § 505(a) of the Act, 21 U.S.C. § 355(a)."

Generally, if the questions presented in a suit for injunction are grave and difficult, and the injury to the moving party will be irreparable if the relief is denied, while the inconvenience and loss to the opposing party will be inconsiderable if the relief is obtained, the injunction should be granted. *Morton Salt Co.* v. *City of South Hutchinson*, 159 F.2d 897, 899 (10th Cir. 1947).

Plaintiff class is in danger of suffering irreparable injury if relief is postponed or denied. Any legal right they might possess to use laetrile may be of academic value if secured only at some undetermined future time. For the terminally ill the phrase "justice delayed is justice denied" contains special significance. Defendants' potential loss from the granting of injunctive relief is slight at most. Certainly defendants are charged with an important responsibility in safe-guarding the public from dangerous drugs, and they are to be commended for pursuing the task diligently. Nonetheless, the danger in the use of nontoxic but unproven cancer treatments by the public "is in their delaying or foregoing diagnosis and treatment which is generally recognized by the medical profession as beneficial and effective." *United States* v. *General Research Laboratories*, 397 F.Supp. 197, 199 (C.D. Calif. 1975). "Where a person is terminally ill with cancer and unresponsive to other treatments, the public harm is considerably reduced." *Carnohan* v. *United States*, Civ. No. 77-0010-GT (S.D. Calif. 1977).

In most instances in which relief in the form of a preliminary injunction is sought, the burden is upon the

movant to establish by clear proof that he will probably prevail when the merits are tried, and that irreparable injury will be suffered unless injunctive relief is granted. *Penn* v. *San Juan Hospital, Inc.*, 528 F.2d 1181, 1185 (10th Cir. 1975); *Crowther* v. *Seaborg*, 415 F.2d 437 (10th Cir. 1969); *Automated Marketing Systems, Inc.* v. *Martin*, 467 F.2d 1181 (10th Cir. 1972). Even under this more stringent standard, injunctive relief would still lie. The record in this case discloses many indications that laetrile may well be established to have been marketed for the last twenty years or more as a cancer treatment, to have been generally regarded by most experts as "safe," even if not "effective," and thus to be exempt from "new drug" classification by virtue of the previously discussed "grandfather clause" provision. Defendants' brief contains references to the report of the Cancer Commission of the California Medical Association published in 1953, which report on its face establishes the longevity of laetrile's recognized use. While concluding that laetrile was ineffectual as a "cure" for cancer, the report generally regarded it as safe and perhaps even palliative to some degree. Interestingly, the 1976 edition of the FDA Code Regulations (21 C.F.R. 121.101(e)(2)), as well as multiple earlier editions, places amygdalin [2] on the "Generally Recognized as Safe List."

Conclusion

Defendants adamantly urge that the use of laetrile is expensive, ineffectual and unjustifiable. Such contentions are serious and cannot be lightly regarded.

Of some significance, however, is the fact that laetrile's high cost is undoubtedly a direct consequence of its illegality in the United States; ironically, this requires travelling all the way to Mexico to enjoy its use lawfully.

This case raises questions of fundamental political and philosophical consequence. Freedom of choice necessarily includes freedom to make a wrong choice, and there is much force to the argument that matters of the type herein under discussion should be left ultimately to the discretion of the persons whose lives are directly involved.

[2] "The Court finds from the record that Laetrile, Amygdalin and Vitamin B-17 are all one in the same, and the term Laetrile will be used to represent all three." *Rutherford* v. *United States*, 424 F. Supp. 105 (W.D. Okla. 1977).

The point can be couched in simple terms. Many intelligent and mentally competent citizens in this nation have made a deliberate decision that they would like to employ an unproven and largely unrespected treatment in an effort to comfort, if not save, lives that orthodoxy tells them have already been lost. They do so with an acute awareness of professional medicine's assessment of their choice. Their decision should be respected.

An appropriate Order will be entered herein.

ORDER AND DECREE

Based upon the Memorandum Opinion filed herein this day,

IT IS HEREBY ORDERED that plaintiff class in the above-captioned case is certified as encompassing all "terminally ill cancer patients." The phrase "terminally ill cancer patient" refers to anyone who, in affidavit form as hereafter described, is declared by a practicing physician (M.D.) to be terminally ill.

Such affidavit shall include the following:

1. that there is histologic evidence of a rapidly progressive malignancy in the patient possessive of a high and predictable mortality rate; and

2. (a) that further orthodox treatment would not reasonably be expected to benefit the patient; or

   (b) that laetrile will be administered only in conjunction with established and recognized forms of cancer treatment; or

   (c) that the patient has made a knowing and intelligent election to take laetrile after being fully apprised of the full range of recognized treatments available and of the fact that laetrile is considered by most cancer experts to be of no value in combating the disease.

IT IS ALSO HEREBY ORDERED that the defendants in this action, the United States of America, its agents, agencies and instrumentalities, including, in their official capacities, Joseph A. Califano, Secretary of Health, Education and Welfare, Donald Kennedy, Commissioner of the Food and Drug Administration, and Vernon D. Acree, Commissioner of U.S. Customs Service, and their successors and agents are enjoined from impeding or preventing the importation and interstate transportation of laetrile by any members of the plaintiff class or their duly designated agents.

IT IS FURTHER ORDERED that such laetrile can be imported and utilized solely for the personal use and benefit of the plaintiff class members.

The Clerk shall send, by registered mail, a certified copy of this Order and Decree to each department administrator referred to herein.

STATEMENT CONCERNING LAETRILE

by

Frank J. Rauscher, Jr., Ph.D.
Director, National Cancer Program
National Cancer Institute

The National Cancer Institute, under the leadership of several Directors, has been deeply concerned with the Laetrile issue. During my tenure as Director, the issue has become a full-fledged public health problem which now, in my estimate, poses a real hazard to cancer patients.

Laetrile is touted by its advocates as a substance which may offer objective and subjective benefits to cancer patients. The basis for such claims is very poorly defined. Perhaps the main offering point, transmitted through extra-scientific channels, is that Laetrile is completely non-toxic and thus can be administered without hazard to patients. The idea of a patient's freedom of choice in selecting therapies is also frequently expressed.

The strength of such appeals is not difficult to understand. Cancer, a group of more than 100 quite different clinical entities, afflicts through death and disability many thousands of individuals yearly. There are few individuals or families who have not been affected directly or indirectly by the occurrence of cancer. There is probably no disease that is feared more or, in spite of the efforts of the work of organizations such as NCI and the American Cancer Society, more poorly understood. Thus, the cancer patient is understandably receptive to the idea that a complex problem can lend itself to a simple solution, in other words, that the disease can be controlled without the discomfort and risk of any non-toxic agent if it cannot be expected to produce objective clinical benefit.

The argument may be made that cancer patients who have failed to respond to other therapies should be allowed to receive Laetrile. The problem with that idea is that the line cannot be so finely drawn. If the drug

can be freely prescribed, many cancer patients who can anticipate cure or effective temporary control of their disease from therapies of demonstrated value will instead seek the uncomplicated solution represented by Laetrile advocates. The time lost can be fatal.

The idea that patients should be allowed to freely select their treatments is, in my mind, a snare and a delusion. In dealing with any medical problem and particularly a dread disease such as cancer, the patient should be able to have the information necessary to select a well-qualified physician who can assure the patient that the best of available diagnostic and therapeutic methods will be applied in the best available facilities. He should have assurance that the properties of the drugs he receives have been well defined. These are complex matters that can be assured only through the effective functioning of complex societal processes, which include medical training and licensure, medical research and careful formal evaluation and regulation of the availability of materials, methods and facilities. These processes may at times be slow and cumbersome but without them there would be little assurance of any quality and effectiveness in medical care. The patient would be fair game for the callous or well-intended advocate of methods that might be ineffective if not harmful.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

Docket No. 77N-0048

IN THE MATTER OF

A RULEMAKING PROCEEDING CONCERNING LAETRILE

AFFIDAVIT OF ROBERT S. K. YOUNG, M.D., Ph.D.

COUNTY OF MONTGOMERY)
) ss
STATE OF MARYLAND)

Before me personally appeared Robert S. K. Young, M.D., Ph.D., who first being duly sworn, deposes and says:

1. I am a physician licensed to practice in the States of Maryland and New York. I received an M.D. Degree from Yale University in 1970. I was an intern at the Mt. Sinai Hospital, New York, New York in 1971.
2. I was an assistant resident in internal medicine at the Mt. Sinai Hospital, New York, New York in 1972.
3. I was a fellow in medical oncology at the National Cancer Institute, National Institutes of Health, Bethesda, Maryland in 1973 and 1974.
4. I am a pharmacologist. I received my Ph.D. from Yale University in 1969.
5. Since 1975, I have been adjunct assistant professor of pharmacology at Georgetown University Schools of Medicine and Dentistry. Since 1975, I have been an instructor of pharmacology in the graduate program, Foundation for Advanced Education in the Sciences, National Institutes of Health, Bethesda, Maryland. My curriculum vitae is attached hereto as Exhibit A.
6. I am Group Leader for the oncologic drug class, Bureau of Drugs, Foods, Food and Drug Administration, Rockville, Maryland.

7. My professional duties require that I be conversant with the scientific literature and methodology in the field of cancer chemotherapy, both therapeutic and experimental, clinical and preclinical, and I am familiar with radiation therapy for cancer.

8. Under Section 107(c)(4) of P.L. 87-781, the 1962 Amendments to the Federal Food, Drug, and Cosmetic Act, Laetrile would not be considered a "New Drug" subject to the requirements of an approved New Drug Application under 21 U.S.C. 355, if each of the following conditions are met:

(a) On October 9, 1962, Laetrile was not a new drug as defined by Section 201(p) of the basic Act as then in force (21 U.S.C. 321(p));

(b) On October 9, 1962, Laetrile was commercially used or sold in the United States;

(c) On October 9, 1962, Laetrile was not covered by an effective (new drug) application under section 505 of the basic Act then in force (21 U.S.C. 355);

(d) Laetrile, as used on October 9, 1962, was the identical drug entity it presently is and

(e) The labeling for Laetrile represents it as being intended solely for use under conditions prescribed, recommended, or suggested in its labeling on October 9, 1962.

In the event that Laetrile does not meet each and every one of these conditions, it is not entitled to the Section 107(c)(4) grandfather exemption from the new drug provisions of the Federal Food, Drug, and Cosmetic Act. Laetrile is not entitled to exemption under this grandfather clause because of numerous changes which have occurred in the composition, labeling, routes of administration, dosage form, intended uses, and identity of the drug substance. Some of these many changes are described and discussed below.

9. I have reviewed and compared labeling and other information contained in the New Drug Application for

Laetrile (NDA 14-032) which the Food and Drug Administration received on October 3, 1962, with labeling for the drug obtained by FDA during an establishment inspection of Krebs Laboratories of San Francisco, California. Exhibit 'B' attached hereto contains excerpts from the New Drug Application which I have reviewed. Exhibit 'C' includes the labeling obtained during the April 23, 1965 inspection.

10. I find that the 1965 labeling is significantly different from that in the 1962 New Drug Application. Among the differences that I noticed are:

(a) The formulation of the drug had been changed. In 1962, the formulation contained N, N diisopropylammonium iodide and saccharides in addition to amygdalin and these materials were to be reconstituted with an isotonic solution. In 1965, the formulation contained only amygdalin and this material was to be reconstituted with water, which is not isotonic.

(b) The class of patients for whom the drug is recommended had been changed. In 1962, the label characterizes the drug as a palliative agent for use in "cancers beyond aid by standard agents," and warns that *"It is not to be employed to the exclusion of surgery, radiation or similar standard modalities so long as they are indicated."* The 1965 labeling states that "Laetrile does not palliate, it acts chemically to kill the cancer cell selectively without injury to the normal tissues of the body." It goes on to warn that "The physician who is using laetrile to palliate his patients is not doing justice to his patient."

(c) The interaction of Laetrile with other forms of cancer treatment had been changed. In 1962, the label states Laetrile "has no known therapuetic incompatibilities." It goes on to warn that "the general enhancement of the clinical condition of the patient is not to be considered as justification for the exclusion of standard modalities so long as they are applicable." In

the 1965 material, the directions state that "The less drugs and medicines given, during the Laetrile treatment, the better. What should be especially avoided is . . . other cancer therapies, strong drugs . . . etc."

(d) The recommended route of administration had changed. In the 1962 labeling, "intravenous administration is preferred." The 1965 labeling advises that "Whenever it's possible to administer Laetrile by injection into the artery supplying the involved area this administration should be used." Specifically, injection into the external carotid or its branches, abdominal aorta, or internal iliac arteries is recommended. The 1965 labeling also recommends injection into the vault of the vagnia and scrotal sac, and rectal enemas. I am generally familiar with the literature and reports relating to Laetrile and am aware that since 1965, there has been commercial distribution of dosage forms of Laetrile including tablets containing Amygdalin, capsules of ground defatted apricot kernels, and a milkshake mix containing Amygdalin all intended for oral use.

(e) The claimed mechanism of action of the drug had changed. In the 1962 material, the "Beardian thesis" was discussed as a theory. The 1962 labeling made no claim that Laetrile is a vitamin or provitamin, or that cancer is a deficiency disease. The 1965 labeling states that "Cancer is a deficiency disease" and there is a presentation of what role amygdalin plays in the therapy of cancer in light of cancer as deficiency disease.

11. All of the above changes are medically important or have medically important implications that must be reviewed scientifically. In the same order as I have reviewed them in 10, they are:

(a) Formulation changes may reflect changes in the drug substance, and always reflect changes in the material to be administered.

Whenever the material to be administered is changed, it is important that the new material be essentially identical to the old material in strength, quality and purity.

(b) The 1962 labeling restricts the use of Laetrile to those patients who all have had conventional therapy, and prescribes use for the purpose of palliation of their disease. The 1965 labeling states that this drug should be used to mitigate the effects of the disease and implies that the drug is of curative value. Since Laetrile has no demonstrable effect on cancer, to use Laetrile in lieu of conventional therapy is to condemn to certain death those patients with curable forms of cancer, and to prolong the pain and suffering of those patients with treatable forms of cancer.

(c) The 1962 labeling warns that conventional therapy not be withheld during Laetrile administration. The 1965 labeling suggests a harmful interaction between Laetrile and conventional therapy. Again, since Laetrile has no demonstrable effect on cancer, to use Laetrile in lieu of conventional therapy is to condemn to certain death those patients with curable forms of cancer and to prolong the pain and suffering of those patients with treatable forms of cancer.

(d) Changes in the route of administration of a drug must always be scientifically validated. A drug may not be effective or may be more toxic when given by different routes of administration. The recommendation in 1965 that the drug be given by intra-arterial injection is particularly hazardous. These high pressure blood vessels are difficult to enter successfully and are prone to continue bleeding after entry with a needle.

(e) The claimed mechanism of action strongly suggest that Laetrile has a rational basis as a can-

cer therapy. Since it has no demonstrable value as a cancer therapy, to suggest that it has may influence some to use it who might not otherwise use it.

12. Discussion of whether the 1962 or 1965 labeling is more accurate or provides safe directions for use of Laetrile is pointless, since the drug is without demonstrable anticancer activity, and is inherently unsafe for use in humans. Because of these changes in Laetrile's labeling alone, it is in no event entitled to the grandfather exemption contained in Section 107(c)(4) of P.L. 87-781.

/s/ Robert S. K. Young, M.D., Ph.D.
ROBERT S. K. YOUNG, M.D., PH.D.

Subscribed and sworn to by the said Robert S. K. Young, M.D., Ph.D., before me this 25th day of March, 1977.

/s/ Mary B. Garrett
Notary Public
My Commission Expires:
July 1, 1978

Dean Burk, March 25, 1977

re FDA Docket No. 77N-0048

DEAN BURK FOUNDATION, INC.
4719 Forty-Fourth Street • Washington, D.C. 20016
Telephone (202) 363-6279

Deposition

TO WHOM IT MAY CONCERN, and in particular, Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, and Tenny P. Neprud, Compliance Regulation Policy Staff, same address.

I am DEAN BURK, President, Dean Burk Foundation, Inc., 4719 44th Street, Washington D.C., and under notaried [sic] oath depose and say, in the following pages (1-7) and attached Exhibits (A-M, 150 pp.), total 157 pp.

(1) I graduated from the University of California at Berkeley in 1923, and received my Ph.D. from that Institution in 1927. This Ph.D. was in the field of biochemistry, in the Department of Plant Nutrition, with a minor in chemistry in the Department of Chemistry.

(2) Prior to my forty-five years employment with the United States Government as a research civil servant (1929 to 1974), I did biochemical and nutritional work at the University of London (University College), Kaiser Wilhelm Institute for Biology in Berlin, Germany, and in the Department of General Physiology at Harvard University (1927 to 1929). I was associated with Cornell University Medical College, New York City, as Associate Professor of Biochemistry from 1939 to 1941.

(3) During my forty-five years of Civil Service with the United States Government, I worked in the Department of Agriculture from 1929 to 1939, and then in the National Cancer Institute of the National Institutes of Health of the Department of Health, Education and Welfare for thirty-five years (1939 to 1974). My last position with HEW before mandatory age-retirement in

1974, was that of Head of the Cytochemistry Section of the National Cancer Institute. I was Guest Scientist at the United States Naval Medical Research Institute, Department of Experimental Medicine, in Bethesda, Maryland from 1974 to 1976.

(4) Attached in Exhibit A, pp. 22-23, is a brief statement of my curriculum vitae listing various awards and appointments in my lifetime to date. I am listed in Who's Who in America and in Who's Who in the World. Approximately 60,000 Americans are listed in the Marquis Who's Who in America; only about 6,000 of these are listed in the Marquis Who's Who in the World, and I am one of them.

(5) I have been active in the field of cancer since 1927, now fifty years, and, in collaboration with several hundreds of scientists and medical doctors, have worked in nearly every field of cancer, and have produced over one hundred and fifty scientific papers in this field alone, out of a total of some 300 scientific papers altogether. Some of this work involved some five years of scientific study in Germany, and some three years of scientific work in England, together with other work and attendance at many international scientific congresses in still other European countries. I have performed tens of thousands of experiments with laetrile.

In the following pages and exhibits I shall attempt to show that, in my opinion, laetrile is generally recognized by qualified experts as a safe and effective treatment for cancer, as a food and vitamin, but not as a "new drug."

In attempting to arrive at a satisfactory distinction between a food and/or vitamin on the one hand, and a new drug on the other, the following considerations must be kept in mind:

(6) Although the Federal Food, Drug, and Cosmetic Act defines in Chapter II—DEFINITIONS—Sec. 201 (321) (g) (1) "The term "drug" means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis,

cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; . . ." nevertheless, foods and vitamins have been widely recognized as exceptions with respect to (A), (B), and (C) (cf. Exhibit A, pp. 4-7).

Thus, in a 15-page letter written on March 1, 1974 by then-FDA Commissioner Alexander M. Schmidt, M.D., to Arthur Koch, National Health Federation, 121 2nd Street, N.E., Washington, D.C. 20002, who had petitioned that fluoride be classified as a drug under the above-cited section of the F.D.C. Act, Commissioner Schmidt denied this petition, stating that

"The petition erroneously concludes that fluoridated water is a drug under the Federal Food, Drug, and Cosmetic Act. It is instead a nutrient, necessary in *normal diets to assure good health*, and is therefore *properly regulated as a food.*"

"The petition misinterprets the definition of "drug" in the Federal, Food, Drug, and Cosmetic Act because it fails to distinguish between *nutritional* (*food*) and *therapeutic* (*drug*) uses of a substance. The petition argues that because the intended use of fluoridated water is aiding in the prevention of a disease, tooth decay, the substance is therefore a drug within the meaning of 21 U.S.C. 321 (pp. 5-9). This proposed interpretation of the statute is inconsistent with the design of the Act, however, and *cannot be sustained.*"

"It is clear that a nutrient, offered as such, was not meant to be treated like a drug under the Act. The interpretation sought to be applied would result in *all food being treated as drugs.* That consequence would follow because the fundamental reason all food is eaten is *to prevent the appearance of diseases that resut from improper diet.* Failure to eat enough food results in protein-calorie malnutrition diseases such as kwashiorkor and maramus. Failure to take in all the proper nutrients results in *vitamin-deficincy diseases like scurvy and pellegra or in other abnormalities.*"

"Underlying this concern for good nutrition is, of course, the intention to prevent disease. . . . General nutritional education does not constitute the specific claims for disease prevention that must accompany a product to make it a drug within the meaning of 21 U.S.C. 321 (g) (1) (B)." . . . "scientific and medical knowledge must be used *to distinguish nutritional from therapeutic uses of a substance.*" (Emphasing italics added).

(7) as a *vitamin* (B-17), amygdalin would be precluded from being classed as a new drug, in view of Congressional Law 94-278 (Proxmire Amendment) signed by the President April 22, 1976, and indeed also by the United States Court of Appeals, 2nd Circuit, decision of August 15, 1974 as upheld by the U.S. Supreme Court by virtue of denial of certiorari. (cf. Exhibit A, pp. 5-10).

Clearly, amygdalin acting as a food and vitamin, and playing a nutrition role in its mechanism of alleviation of human cancer, requires no designation as a new drug, any more than does vitamin C (ascorbic acid) in its mechanism of alleviation of scurvy, and similarly through the list of all other vitamins, as well as nearly all foods.

Let us now examine how the foregoing general considerations of (6) and (7) do in fact apply to the case of laetrile in particular, as a food and as a *vitamin*, and not a new drug.

(8) In the decision of the United States Court of Appeals, 10th Circuit (75-1725), the opinion is given that "As we view it, the reason that the Food and Drug Administration is anxious to classify Laetrile as a new drug is so as to bring it within the new drug certifications procedures of the Food, Drug and Cosmetics Act. Section 505(a) of the Act, 21 U.S.C. Section 355(a). This provision bars the introduction into interstate commerce of a new drug without an approved new drug application having been filed pursuant to the Act just cited." But, "the FDA's record is grossly inadequate and consists merely of a conclusory affidavit of an official of the FDA which in effect declares it (laetrile) *is a new drug because the FDA says it is* and thus is subject to all of the statutory vagaries of such a designation." (October 12, 1976).

Subsequently, upon remand to the United States District Court for the Western District of Oklahoma, Judge Bohanon in a Jan. 4, 1977 MEMORANDUM OPINION AND ORDER ordered that "pursuant to 5 U.S.C. Paragraph 705, that while this case is on remand to the FDA, and until such time as the FDA proffers to the Court an administrative record containing substantial evidence of its determination that Laetrile is a "new drug" under the terms of the relevant statute, *such determination is held to be without force or effect* as to the plaintiff class in this case," and that hereafter "this suit shall be certified and treated as a class action suit," under Rule 23 of the Federal Rules of Civil Procedure. Further, the Court stated, "Based on the complete absence of any evidence tending to establish a rational basis for the agency's determination, the Court would also be compelled to find, in applying the standards of 5 U.S.C. Paragraph 706, that the agency's determination was arbitrary, capricious," and represented "an abuse of discretion," and that it should be overturned for these additional reasons.

(9) To the judiciary considerations briefly outlined in (8), I may add that, in my judgment and experience, the FDA determination is scientifically without substantial basis, arbitrary, capricious, merely conclusory without evidence, and, I affirm, prevaricative, to an unbelievable degree, as indicated below. FDA officials and FDA outside appointees have made innumerable statements to the effect that laetrile is not a vitamin, but always, to my knowledge, in merely conclusory manner with clear and intended *neglect of overwhelming evidence to the contrary*, some of which I shall present in attached Exhibits for any and all to see and study. To paraphrase the wording of the 10th Circuit Federal Appellate Court, "because the FDA conclusorily declares that laetrile is not a vitamin (B-17) does not make it not a vitamin." As pointed out in (7) above, the status of laetrile as a vitamin (B-17), to be indicated below, proscribes and makes moot its being a new drug.

Laetrile as Vitamin

(10) To begin with, all vitamins are by Federal statute definition foods (cf. Exhibit A, pp. 1-2, 5-10); and,

as indicated in Exhibit B, laetrile is listed * in the HEW-FDA GRAS List (foods *"Generally Regarded as Safe"*) under the heading of natural extractive from bitter almond, apricot, or peach kernels (syn. seeds, nuts). The only specified proviso is that such extractive be "free from prussic acid." Exhibit C summarizes evidence that laetrile contains no ordinarily measurable or measured quantity of prussic acid, any and all statements to the contrary notwithstanding. Being on the GRAS List proscribes laetrile from being classified as a food *additive*, in accord with the Federal statute definition in the Federal Food, Drug, and Cosmetic Act—Chapter II, Definitions—Sec. 201(321)(s).

(11) To continue, pp. 18-21 of Exhibit A, summarizes the extensive evidence that has existed for over one hundred years, that laetrile, at conventionally applied dosages for cancer treatment is nontoxic in animals and man over a very wide range of application.

(12) Pp. 7-9 of Exhibit A gives a widely accepted definition of vitamins and their varying natures, background, and interpretation. The summarized definition at the top of p. 8 is in close harmony with that given by Professor David M. Greenberg, Emeritus University of California Medical School, and Consultant, Cancer Advisory Council, California State Department of Health, on p. 346 of his article in Western Journal of Medicine, vol. 122, May 1975, but Professor Greenberg makes in this article a studied neglect of his definition to the instance of laetrile data of the vitaminic nature of laetrile now to be reported, briefly summarized on p. 15 of Exhibit A, following discussion on pp. 11-14.

Animal data.

(13) p. 15 of exhibit A sumamrizes amygdalin efficacy against cancer in animals as observed in three widely separated countries of the world, and five laboratories therein, up to date of 1975; more such work has appeared since. Not all such data can be presented here—

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* P. 372 of the 1976 edition of FDA Code Regulations, Title 21 CFR 121.101(o)(2), and eariler editions.

by any means—but it may be illustrated in Exhibits D, E, and F as follow.

Exhibit D sets forth some of the data referred to in Item (1), p. 15, Exhibit A, taken by Dr. Kanematsu Sugiura, Sloan Kettering Cancer Center (New York).

Exhibit E sets forth some of the data referred to in Item (2), p. 15, Exhibit A, taken by the Southern Research Institute (Birmingham, Alabama) for the National Cancer Institute, concluding with statistical confirmations by others than myself.

Exhibit F sets forth a small fraction of the data taken by the Scind Laboratories (San Francisco), 1968.

In (13) above and (14) below, laetrile shows all the essential properties and attributes that define a *vitamin*, (cf. Exhibit A, p. 8, and p. 11; and Greenberg, J. West. Med. 122, p. 346, 1975) and, in this instance, a B vitamin: it is virtually nontoxic, water-soluble, an exogenous nutrient or food factor, and active in relatively small, essentially catalytic, non-calorific amounts, and is essential or beneficial in normal metabolism and/or physiologic functioning to *overcome deficiency lesions and symptoms of nutritional disease.* In the foregoing animal data the deficiency lesions and symptoms of nutritional disease are best illustrated by the action of amygdalin in lengthening of animal lifetime or decreasing development of metastases, or both, and increase in health and well-being, all properties objectively measured in the experiments reported, as may readily be seen upon detailed examination of the data.

Human data.

(14) Some of the first, clear-cut published data indicating a positive and vitamin action in humans was reported by the Cancer Commission of the California Medical Association in 1953 (California Medicine, 78, 320-326) and later republished by the California State Department of Health Cancer Advisory Board in 1963 et seq., which reported in a study of 44 terminal cancer patients that "all of the physicians whose patients were reviewed spoke of increase in the sense of well being and appetite, gain in weight, and decrease in pain (cf. Exhibit A,

bottom of p. 11 et seq.). Although the Commission regarded all of these criteria of action as being only subjective (an aspect not essentially material to definition of a vitamin), nevertheless all of these criteria are in principle objective also, as "perceptible to persons other than the patient" (dictionary definition of (objective"). [sic] The Commission also acknowledged a probable effect on nitrogen metabolism.

Since 1953, and to some extent before, scores of publications throughout the world have reported thousands of patients who appear from observing physicians' reports to have benefitted objectively as well as subjectively from administration of laetrile. It is idle to declare that such observations are totally without value, medically or scientifically, even if they do not represent ideal methods of ascertaining probable cause and effect relationship, which is, indeed, seldom if ever attained in the field of human cancer, any and all statements to the contrary notwithstanding. In any event, widely varying opinions on this aspect prevail in the field of medicine, to such an extent that no one opinion can as yet be said to be definitive and universally accepted, and probably never will be. In forthcoming weeks a book will appear by Dr. John Richardson, M.D. on his experiences with some 5000 cancer patients receiving laetrile along with related treatments, and somewhat later on a similar report by Dr. Ernesto Contreras is scheduled based on about the same number of patients. And, during the past year the Governments of Australia and Israel have set up clinical testing of laetrile on human cancer patients, based upon inspection visits by respective government medical appointees to study results and clinics of Drs. Richardson and Contreras and other medical centers in the United States and elsewhere, which Australian-Israel testing would not have been set up without solid basis, results of which must be awaited.

Exhibit G reports laetrile clinical experiences of the leading German laetrile specialist, Dr. Hans Nieper, Hannover, Germany, from early 1971 to 1977. It is to be noted from the letter that most laetrile medical specialists do not use or recommend exclusive treatment by laetrile but in a setting of metabolic therapies, in all of which laetrile is regarded as vitamin (B-17), which, as in most vitamin regimens involves usually interrelated treatment with a number of other vitamins, since the action of a vitamin does not take place in a vacuum, but in a proper reasonable balance of other vitamins and indeed other foods.

In all or nearly all of the Legislature Hearings on the Alaska type laetrile bills (cf. Exhibit M) so far held in Maryland, Nevada, Washington, Arizona, Indiana, and South Dakota, patients testified personally who had undergone various forms of laetrile treatment after it had become evident that conventionally approved therapies were failing of successful result, and who were now surpassing the M.D.-predicted probable survival times, and many of them presented documented histories of their earlier and more recent statuses, from which it appeared that laetrile was having benefit. Again, ideal cause and effect relationships were not sought with laetrile any more than with conventional chemotherapeutic treatments. Petition compaigns to introduce "Alaska-type" bills are now underway in Florida, Hawaii, Texas, Ohio, Wisconsin, Louisiana, Massachusetts, Michigan, New Jersey, New York, North Carolina, Oklahoma, Kansas, Iowa, Illinois, and will almost certainly involve patients and documentation of the type just described in the already active Legislatures, where in the Committee Hearings and votings by one house or the other, the voting in favor of an "Alaska-type" bill has been overwhelming or nearly so, with failure in but one state, North Dakota.

Exhibit H presents a history of the initial representation of laetrile as a vitamin (B-17), involving human epidemiological considerations as well as animal indications, and Exhibit I briefly presents a recent summary of some current aspects. Exhibit J gives some indication of the extent of laetrile availability in the United States, some 1500 kg. of which are consumed per month by some 50,000 Americans. At least 200 kg. per month are manufactured in the United States. As indicated earlier, the 10th Federal Circuit has enjoined the FDA provisionally from preventing interstate commerce restrictions of dis-

tribution, etc., on the basis that the FDA must first produce evidence (administrative record) to justify any classification of laetrile as a New Drug; meanwhile laetrile remains simply a food by Federal Statutory definition, legally available in the United States as a food, and subject only to FDA Food (not New Drug) regulations, which are far less stringent.

As a vitamin (a class of food), laetrile cannot be classed by the FDA as a New Drug (or food additive), in any event, as indicated in (7) above. At the same time, this would render the question of "grandfathering" laetrile as a New Drug as now moot and superfluous. Exhibits K and L may be of interest in this connection, however, as they concern the use of laetrile in the treatment of cancer before 1962 and 1938 in the United States (cf. (8) above), i.e., before passage of the Kefauver and Copeland Amendments to the Federal Food, Drug, and Cosmetic Act.

Respectfully submitted as verified copy, in quadruplicate,

/s/ Dean Burk
DEAN BURK,
President, Dean Burk Foundation, Inc.
National Cancer Institute, 1939-1974, Ret.

Subscribed and sworn to before me this 25th day of March, 1977.

/s/ [Illegible]
Notary Public
My Commission Expires:
Dec. 11, 1977

EXHIBIT I

Deposition

TO WHOM IT MAY CONCERN:

My name is Raymond Ewell of 56 Highgate Ave., Buffalo, New York. I hold a Ph.D. degree in chemistry from Princeton University and other degrees from Purdue University, George Washington University and the University of Toledo. From 1957 to 1973 I was vice-president for research, professor of chemistry and professor of chemical engineering at the State University of New York at Buffalo. Also, I lectured in a course in human nutrition in the Department of Biology. I retired in 1973 and since then I have worked part-time for the United Nations on problems of agriculture.

The first statement I want to make is that all the available facts indicate that *amygdalin* is essentially nontoxic to laboratory animals and to humans. Anyone who claims that amygdalin is a toxic substance is indulging in sophistry or pseudo-science or has never examined the facts. Amygdalin does have a very low toxicity, comparable to many foods such as salt, sugar, spices, condiments (e.g. MSG), and even some fruits and vegetables. All foreign substances have some toxicity in the animal organism, but many substances have very low toxicity and are therefore classified as GRAS (Generally Recognized As Safe). *Amygdalin* has never been classified as GRAS or not as GRAS primarily because only a few people consume *amygdalin* in its pure form either as a food supplement or as a flavoring agent. However, many people in many parts of the world consume substantial amounts of amygdalin as a component of almonds, fruit seeds, buckwheat, tapioca, lima beans and many other foods. The candy called "Marzipan" is especially rich in amygdalin reportedly as high as 20% amygdalin.

Amygdalin is a well-known organic chemical compound with the overall formula $C_{20}H_{27}O_{11}N$. It is called amygdalin because it was first isolated from almonds and identified by German chemists in 1830 (amygdalo is the

Greek word for almond). Correct chemical names for amygdalin are mandelonitrile diglucoside or mandelonitrile gentiobioside. Amygdalin is also known popularly as laetrile or Vitamin B-17. Pure amygdalin is manufactured by several reputable biochemical firms in West Germany, Switzerland, Italy, Monaco and Mexico. Amygdalin is made by alcohol extraction of apricot kernels or almonds followed by crystallization from the alcohol solution. Amygdalin has recently been approved by the Govern-[sic]

Amygdalin is a definite molecular compound comprising one benzaldehyde unit, one cyanide unit and two glucose units, firmly bound together in a molecule. Saying that amygdalin is toxic because it contains cyanide is like saying that common salt is toxic because it contains chlorine, which is a poison. However, we know that salt is only slightly toxic, even though large quantities of salt can be toxic to animals or humans (but not because it contains chlorine).

Moreover, a number of normal components of the human body contain cyanide. For example, Vitamin B-12 is essential to human health, and the Vitamin B-12 molecule contains cyanide in the same way that amygdalin contains cyanide.

I have had no first-hand experience in toxicity studies on *amygdalin*, but I have read reports from the Sloan-Kettering Institute (New York), Southern Research Institute (Birmingham, Alabama), Scind Laboratories (San Francisco) and laboratories in France, West Germany and Switzerland giving test results on animals showing that amygdalin is essentially non-toxic. One of these reports (I believe it was the Sloan-Kettering Institute) stated that the first slight indication of toxicity was noted in animal tests corresponding to 75 grams (3 ounces) of amygdalin per day for a 165 lb. man. Significant toxicity was noted at 150 grams (6 ounces) of amygdalin per day for a 165 lb. man. Many GRAS substances are toxic at these high levels. Most people who use amygdalin as a food supplement consume less than one gram per day, and even in cases where doctors have recommended intakes of 2 to 5 grams per day of amygdalin, no toxicity has ever been noted. Even 5 grams per day is only 1/15 of the level of 75 grams per day where Sloan-Kettering Institute noted the first slight indication of toxicity.

The California State Department of Health has recorded several cases where eating large numbers of apricot kernels have caused illness (but not deaths), and this illness has been attributed to *amygdalin* by some persons, although not by the California State Department of Health. The types of apricot kernels available in California contain 1% to 2% amygdalin, the rest of the kernel being composed of proteins, enzymes, fats, cellulose, lignin and other natural chemical compounds. It would be jumping to conclusions to conclude that the illness referred above was caused by amygdalin instead of one or more of the other chemical compounds in apricot kernels. In other words one has to make a distinction between the essentially zero toxicity of pure amygdalin and the potential toxicity of complex natural substances.

One personal reason that leads me to believe that *amygdalin* is non-toxic is that for several years I have taken 1 gram of pure amygdalin per day (500 miligrams enough amygdalin for good health. One gram of pure amygdalin is equivalent to about 250 almond kernels. Also, I eat apricot kernels, almonds and buckwheat both for flavour and for their amygdalin contents.

/s/ Raymond Ewell
RAYMOND EWELL, PH.D.
Date—Dec. 13, 1976

REPUBLIC OF AUSTRIA)
CITY OF VIENNA)
) SS
EMBASSY OF THE)
UNITED STATES OF AMERICA)

Subscribed and sworn to before me Richard E. Schroeder, Vice Consul of the United States of America in and for Austria, duly commissioned and qualified, this 13th day of Dec., 1976.

/s/ Richard E. Schroeder
RICHARD E. SCHROEDER
American Vice Consul

[SEAL]

IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF OKLAHOMA

No. CIV 75-0218-B

GLEN L. RUTHERFORD, individually and on behalf of a class composed of terminally ill cancer patients,
PLAINTIFFS

v.

UNITED STATES OF AMERICA, JOSEPH A. CALIFANO, Secretary of Health, Education, and Welfare; DONALD KENNEDY, Commissioner of the Food and Drug Administration, *et al.*, DEFENDANTS

AFFIDAVIT OF GERALD M. RACHANOW

Gerald M. Rachanow, being duly sworn, deposes and says:

1. I am a Consumer Safety Officer in the Bureau of Drugs, Office of Compliance, United States Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland.

2. I have reviewed the physician's affidavits intended to support the importation of Laetrile for delivery to and the personal use of sixteen persons. These affidavits designate Cyto Pharma U.S.A., 146 Main Street, Suite 405, Los Altos, California 94022, and various treating physicians as the patients' duly designated agents for the purposes of importation and interstate transportation of the Laetrile. The sixteen affidavits are for a total of 2146 3-gram vials and 9600 500 mg. tablets of Laetrile. The import shipment is identified as entry number 127199. Copies of the sixteen affidavits are attached hereto as Exhibit 1.

3. On August 12, 1977, instructions were given to FDA district offices to contact these sixteen patients and to ascertain whether the patients had received all or any of the Laetrile ordered; how much, if any, of the order

was outstanding; and how much of the Laetrile they desired to receive now.

* * * * *

5. FDA investigators were able to contact all of the patients or members of their families except one, and the investigators either obtained a signed statement (affidavit) or prepared memoranda in the usual course of business recording what transpired.

* * * * *

7. Of particular interest is the information obtained from Herman Dillingham, son of Aaron Dillingham. He stated that he placed an order for 56 ampoules for his father in July 1977 and that he paid $588.00 ($10.50 per ampoule) in advance to cover the whole shipment from Mexico. He did not mention ordering any tablets, yet the physician's affidavit indicates that 750 tablets were ordered. Further, the physician's affidavit is signed in the name of Aaron Dillingham and indicates that the physician conducted a thorough medical examination of the patient on July 8, 1977. Since the son has stated that he placed the Laetrile order for his father, we cannot establish that a bona fide physician-patient relationship existed in this case.

The motives of the supplier are also in question as regards this patient. When contacted by telephone on August 11, 1977 by a person representing the agent, Cyto Pharma, U.S.A. (Los Altos, California), Herman Dillingham indicated that he did not wish to receive any tablets; however, the Cyto Pharma, U.S.A., representative stated to him that his father may need the tablets also at a later date so they would get the entire order as originally placed. (See Exhibit 3).

* * * * *

9. Some of the information obtained from these patients or their families is of particular interest. Mabel Gulbrandson's sister informed the investigator that she has been using Laetrile for about 15 months and receives it on a regular basis. From the sister's comments, it appears difficult to ascertain whether or not this patient is using the injectable Laetrile. (See Exhibit 5).

10. J. M. Richards', Jr., wife signed an affidavit that a 2½ month supply of Laetrile consisting of 300 tablets was purchased while in Ponca City, Oklahoma on June 6, 1977. It should be noted that the affidavit purportedly intended for this shipment was dated June 6, 1977 (for 150 vials and 650 tablets), that the 300 tablet supply of Laetrile tablets was purchased on June 6, 1977 and that Mrs. Richards does not mention any order being outstanding. (See Exhibit 13).

11. J. B. Gray provided an affidavit stating that in June 1977 he went to the Gibson Clinic in Ponca City, Oklahoma and upon his return home (in June 1977) he brought with him a six month supply of Laetrile. He further stated that he does not intend to reorder until December 1977 and that he does not want any of the Laetrile ordered via the affidavit dated June 1, 1977. It should also be noted that Mr. Gray stated that he signs all legal documents as "Jasper B. Gray" and that he has no idea how the signature J. B. Gray appeared on the June 1, 1977 Laetrile affidavit. (See Exhibit 14).

* * * * *

13. Thelma Brashear signed an affidavit that she received a four month supply of Laetrile tablets (around July 1, 1977) when she completed treatment at the Gibson Clinic in Ponca City, Oklahoma and that she has no outstanding order. Although her affidavit calls for 150 vials and 650 tablets as a six month supply, she stated that she received only a four month supply of tablets and there is no mention of receiving any vials. (See Exhibit 15).

* * * * *

19. From the above stated facts, it appears that very little of the Laetrile covered by these sixteen affidavits is intended for delivery to or the personal use of the patients identified in the affidavits. It would appear that this Laetrile supply would constitute an inventory from which the agents involved could supply Laetrile to other patients, with or without an affidavit, there being no way to control such substitute consignment.

20. It appears that at least one designated agent, a treating physician, e.g., Robert W. Gibson, M.D., Ponca

City, Oklahoma, has been maintaining an inventory of Laetrile and furnishing it to patients at his clinic in Ponca City when the patients visit him. (See Exhibits 12, 13, 14, 15 and 16). It further appears that the Laetrile is provided to the patients near the time that the affidavit for importation is executed, prior to the affidavit ever being provided to Customs officials to "legally" import the Laetrile.

21. One patient's wife, Mrs. Kenneth Wilson, stated to the investigator that most of the tablets which her husband could not take were returned to the supplier. Did these tablets then form part of an inventory? Were they subsequently provided to another patient? There appears to be no way of knowing about or monitoring occurrences of this type.

I certify under penalty of perjury that the foregoing statement is true and correct. Done this 18th day of August, 1977.

/s/ Gerald M. Rachanow
GERALD M. RACHANOW
Consumer Safety Officer

EXCERPT FROM THE TRANSCRIPT OF ORAL ARGUMENT BEFORE THE COMMISSIONER May 22, 1977

[311] Well, actually, you are going to go back and prepare your foods just exactly like your great-great grandparents prepared their foods. And they had every bit of the stuff and they were alive and they didn't have cancer.

(Applause.)

MR. RUTHERF0RD: In January or March of 1972, I wrote the following paragraph. It went to my Congressman; it went to my Senators. I got very few answers.

I said, "The Federal Food and Drug Administration has known about laetrile since 1940. Yet in all this time, FDA has refused to produce specific tests conducted by the FDA in regards to laetrile. The FDA has consistly refused to allow the use or the testing of laetrile by anyone, even on an experimental basis, in the United States. The FDA says that it is a poison. I have been on the laetrile program since December 22, 1970 with no side effects until the present moment. I injest anywhere from one 500 milligram tablet or 1/2 gram to as high as nine of them in a day's time depending on what this carcass is telling me and I've learned to read the signals about what my body does tell me.

"May I remind the FDA that cobalts, cytoxin and all the chemotherapeutic drugs are all deadly in their own right. But the FDA allows them to be used. Why?"

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SUPREME COURT OF THE UNITED STATES

No. 78-605

UNITED STATES, ET AL., PETITIONERS

v.

GLEN L. RUTHERFORD, ET AL.

ORDER ALLOWING CERTIORARI

Filed January 22, 1979

The petition herein for a writ of certiorari to the United States Court of Appeals for the Tenth Circuit is granted.

☆ U. S. GOVERNMENT PRINTING OFFICE: 1979 288208 357